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Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2026–N–8249]

Gastroenterology-Urology Devices; Reclassification of Diagnostic Endoscopic Light Source Systems To Be Renamed Cystoscopic Systems Intended as an Aid for Detection of Bladder Cancer

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed amendment; proposed order; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify diagnostic endoscopic light source systems (product code OAY), which are postamendments class III devices, from class III (premarket approval) into class II (special controls), subject to premarket notification. FDA is also proposing a new device classification regulation with the name ''Cystoscopic system intended as an aid for detection of bladder cancer,'' along with special controls that FDA believes are necessary to provide a reasonable assurance of the safety and effectiveness of these devices.

DATES: Either electronic or written comments on the proposed order must be submitted by October 16, 2026. Please see Section X of this document for the proposed effective date when the new requirements would apply and for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 16, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2026–N–8249 for ''Gastroenterology-Urology Devices; Reclassification of Diagnostic Endoscopic Light Source Systems To Be Renamed Cystoscopic Systems Intended as an Aid for Detection of Bladder Cancer.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf* .

Docket: For access to the docket to read background documents, the plain language summary of the proposed order of not more than 100 words consistent with the ''Providing Accountability Through Transparency Act,'' or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Esther Kaplan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2604, Silver Spring, MD 20993, 301–796–1863, *Esther.Kaplan@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) establishes three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Section 513(a)(1) of the FD&C Act defines the three classes of devices. Class I devices are those devices for which the general controls of the FD&C

Act (controls authorized by or under sections 501, 502, 510, 516, 518, 519, or 520 (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, or 360j) or any combination of such sections) are sufficient to provide reasonable assurance of safety and effectiveness of the device; or those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance, but because the devices are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury, are to be regulated by general controls (section 513(a)(1)(A) of the FD&C Act).

Class II devices are those devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, and for which there is sufficient information to establish special controls to provide such assurance, including the issuance of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions FDA (the Agency or we) deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act).

Class III devices are those devices for which insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness, and are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act).

Devices that were not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976 (generally referred to as ''postamendments devices'') are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA action. Those devices remain in class III and require approval of a premarket approval application (PMA), unless and until: (1) FDA reclassifies the device into class I or II, or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of the premarket notification procedures in section 510(k) of the FD&C Act and part 807, subpart E, of FDA's regulations (21 CFR part 807, subpart E).

A postamendments device that has initially been classified into class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA, acting by administrative order, can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.[1]

FDA relies on ''valid scientific evidence,'' as stated in section 513(a)(3) of the FD&C Act and defined in 21 CFR 860.7(c)(2), in the classification process to determine the level of regulation for devices.[2] In general, to be considered in the reclassification process, the ''valid scientific evidence'' on which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information; *e.g.,* the contents of a pending PMA (see section 520(c) of the FD&C Act). Section 520(h)(4) of the FD&C Act provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of the device, but it does not include the descriptions of methods of manufacture and product composition and other trade secrets.

In accordance with section 513(f)(3) of the FD&C Act, the Agency is issuing this proposed order to reclassify postamendments class III diagnostic endoscopic light source systems intended for use with an approved optical imaging agent for photodynamic blue light cystoscopy as an adjunct to white light cystoscopy for the detection of known or suspected bladder cancer, including carcinoma in situ, or in patients undergoing surveillance cystoscopy for bladder cancer (product code OAY),[3] hereinafter referred to as cystoscopic systems intended as an aid for detection of bladder cancer, into class II (special controls), subject to premarket notification, under a new device classification regulation with the name ''Cystoscopic system intended as an aid for detection of bladder cancer.''

Based on the PMA data available to FDA in accordance with section 520(h)(4) of the FD&C Act,[4] [5] published peer-reviewed literature, data and information from a public meeting of the Oncologic Drugs Advisory Committee (ODAC) held on December 17, 2009, to discuss NDA 022555 for CYSVIEW (hexaminolevulinate hydrochloride) for Intravesical Solution [6] (CYSVIEW (hexaminolevulinate hydrochloride)) for use with the Karl Storz Photodynamic Diagnostic D-Light C System (PDD System) (P050027), a cystoscopic system intended as an aid for detection of bladder cancer, and data available to the Agency demonstrating a lack of significant postmarket safety signals, FDA believes there is sufficient information to reclassify cystoscopic systems intended as an aid for detection of bladder cancer from class III (premarket approval) into class II (special controls).

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[1] See generally section 513 of the FD&C Act.

[2] See generally *id.*

[3] FDA's Center for Devices and Radiological Health (CDRH) uses product codes to assist in accurate identification and tracking of current medical devices and to allow for tracking of and easy reference to predicate device types. CDRH and a subset of Center for Biologics Evaluation and Research regulated medical device product codes consist of a three-letter combination that associates a device's type with a product classification designated for the application. There is no definitive meaning for the three-digit classification product codes in CDRH's Product Classification Database. See FDA guidance titled ''Medical Device Classification Product Codes,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-classification-product-codes-guidance-industry-and-food-and-drug-administration-staff.*

[4] In proposing to reclassify, on its own initiative, cystoscopic systems intended as an aid for the detection of bladder cancer from class III to class II, FDA is relying on data from the relevant PMA available to FDA in accordance with the six-year rule (see section 520(h)(4) of the FD&C Act) (see also, FDA's guidance titled ''Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997—Guidance for Industry and for FDA Reviewers''), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-section-216-food-and-drug-administration-modernization-act-1997-guidance-industry-and-fda.* This data was from a PMA approved after November 28, 1990, and before July 24, 2020, for this specific proposed reclassification as noted in section II of this proposed order. See also FDA's premarket approval database, available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm.*

[5] For the purpose of this proposed order, PMA data considered in accordance with section 520(h)(4) includes only that data which was submitted to and therefore considered by FDA at the time the PMA was reviewed and approval was issued.

[6] At the time of the ODAC meeting, the proposed trade name for the cross-labeled drug was HEXVIX (hexaminolevulinate hydrochloride) Kit.

FDA believes the standard in section 513(a)(1)(B) of the FD&C Act is met as general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of these devices, and there is sufficient information to establish special controls, which, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of these devices.[7] Therefore, FDA is proposing to establish a new device classification regulation, ''Cystoscopic system intended as an aid for detection of bladder cancer,'' and classify this device type into class II along with the special controls that the Agency believes are necessary to provide a reasonable assurance of the safety and effectiveness of these devices.

Under the FD&C Act, premarket notification (510(k)) submissions are required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt from 510(k) requirements under section 510(m) of the FD&C Act.[8] FDA has not made this determination for cystoscopic systems intended as an aid for detection of bladder cancer, and therefore, FDA is not proposing that this class II device type be exempt from 510(k) requirements. If this proposed order is finalized, persons who intend to market this type of device will have to submit to FDA a premarket notification under section 510(k) of the FD&C Act and receive clearance prior to marketing the device.

[7] FDA notes that the ''ACTION'' caption for this proposed order is styled as ''Proposed amendment; proposed order; request for comments,'' rather than ''Proposed order.'' Beginning in December 2019, this editorial change was made to indicate that the document, if finalized, will amend the Code of Federal Regulations. The change was made in accordance with the Office of the Federal Register's (OFR) interpretations of the **Federal Register** Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

[8] In considering whether to exempt class II devices from premarket notification, FDA considers whether premarket notification for the type of device is necessary to provide reasonable assurance of safety and effectiveness of the device. FDA generally considers the factors initially identified in the January 21, 1998, **Federal Register** notice (63 FR 3142) and further explained in FDA's guidance issued on February 19, 1998, titled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-class-ii-device-exemptions-premarket-notification-guidance-industry-and-cdrh-staff,* in determining whether premarket notification is necessary for class II devices. FDA also considers that even when exempting devices from the 510(k) requirements, these devices would still be subject to certain limitations on exemptions, for example, the general limitations set forth in 21 CFR 876.9.

II. Regulatory History of the Device

In accordance with section 513(f)(1) of the FD&C Act, cystoscopic systems intended as an aid for detection of bladder cancer were automatically classified into class III because they were not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, have not been reclassified into class I or class II, and have not been found substantially equivalent to a device placed in commercial distribution after May 28, 1976, which was subsequently classified or reclassified into class II or class I. Therefore, they are subject to the PMA requirements under section 515 of the FD&C Act (21 U.S.C. 360e).

On May 28, 2010, FDA approved an original PMA for the PDD System (P050027) (Ref. 1), which is the first approved cystoscopic system intended as an aid for detection of bladder cancer. The PDD System, when used in combination with the approved optical imaging drug CYSVIEW (hexaminolevulinate hydrochloride) (New Drug Application (NDA) 022555), was approved with an indication for photodynamic blue light cystoscopy, as an adjunct to white light cystoscopy for the detection of non-muscle invasive papillary cancer of the bladder in patients suspected or known to have the lesion on the basis of a prior cystoscopy (Ref. 1). The device is only to be used as an adjunct to white light cystoscopy (Ref. 2) and, therefore, is not intended to be used as the sole or definitive basis for diagnosis.

Approval of the PMA for the PDD System occurred on the same day as the approval of the NDA for CYSVIEW (hexaminolevulinate hydrochloride), consistent with recommendations made by the ODAC. On December 17, 2009, the ODAC met to discuss the benefit/risk assessment for CYSVIEW [9] (hexaminolevulinate hydrochloride), when used with the PDD System, for photodynamic blue light cystoscopy performed as an adjunct to white light cystoscopy in the detection of non-muscle invasive papillary cancer of the bladder in patients with known or suspected bladder cancer (Ref. 3). Discussion by the ODAC members included considerations applicable to the PDD System (*e.g.,* the risk of false positives) as part of the combined use of the two products. The ODAC was presented with data that included results from a prospective, controlled clinical trial of adult subjects with known or suspected bladder cancer, as well as data from several supportive studies. The majority of ODAC members found that the data established a favorable diagnostic benefit-risk assessment for CYSVIEW (hexaminolevulinate hydrochloride) when used in combination with the PDD System for the detection of non-muscle invasive papillary cancer of the bladder in patients with known or suspected bladder cancer. Although several ODAC members expressed concerns about potential repetitive use of CYSVIEW (hexaminolevulinate hydrochloride), these concerns related to use of the drug and not specifically the PDD System. In a September 3, 2010, **Federal Register** notice (75 FR 54154), FDA announced the PMA approval order and the availability of the Summary of Safety and Effectiveness Data (SSED) for the device.

FDA's approval of the PDD System included a postmarket study commitment for a prospective, randomized, controlled clinical study to assess the safety and efficacy of CYSVIEW (hexaminolevulinate hydrochloride) in the detection of carcinoma in situ of the bladder (Ref. 1).[10] On February 15, 2018, FDA approved a PMA supplement to the PDD System (P050027/S011), supported by clinical data from the postmarket study results, which, among other things, added an additional subsystem that included a flexible video cystoscope and expanded the indications for use for the device to include use in combination with CYSVIEW (hexaminolevulinate hydrochloride) for detection of carcinoma in situ of the bladder and in patients undergoing surveillance cystoscopy for bladder cancer.[11] The approval of this PMA supplement was consistent with changes to the labeling for CYSVIEW (hexaminolevulinate hydrochloride) approved on the same day (NDA 22555/S–005) (Ref. 4).

As of the date of issuance of this proposed order, fewer than 6 years have passed since FDA's approval of certain other PMA supplements for the PDD System. Therefore, in accordance with the ''six-year rule'' described in section 520(h)(4) of the FD&C Act, no information from these documents has been used in support of this proposed

[9] See FN 6.

[10] Postmarket study requirements also included a prospective, randomized, controlled clinical study to assess the safety and efficacy of CYSVIEW (hexaminolevulinate hydrochloride) for repetitive use.

[11] Additional information regarding this PMA supplement is discussed in a petition for reclassification submitted by the manufacturer of the PDD System on October 21, 2022, under Docket Number FDA–2022–P–2644.

order to reclassify cystoscopic systems intended as an aid for detection of bladder cancer into class II. In addition, since the first approval order for a cystoscopic system intended as an aid for detection of bladder cancer, FDA has received no other original PMAs for this device type.

On April 29, 2015, FDA published a notice in the **Federal Register** (80 FR 23798) titled ''Retrospective Review of Premarket Approval Application Devices; Striking the Balance Between Premarket and Postmarket Data Collection.'' This notice announced the Center for Devices and Radiological Health's progress on its 2014–2015 strategic priority, ''Strike the Right Balance Between Premarket and Postmarket Data Collection'' (Ref. 5). As part of that strategic priority, FDA was at that time conducting a retrospective review of all PMA product codes with active PMAs approved prior to 2010 to determine whether, in light of FDA's then-current understanding of the technology, there may be sufficient information to establish special controls to provide a reasonable assurance of safety and effectiveness for these devices, together with general controls, supporting reclassification of these devices from class III to class II. FDA solicited comments on certain product codes that had been identified at that time, including devices in product code OAY, as candidates for reclassification (Ref. 6). FDA received no comments on the notice about the potential reclassification of devices in product code OAY.

In October 2022, FDA received a petition from the manufacturer of the PDD System requesting that FDA reclassify devices under product code OAY from class III to class II (the Reclassification Petition) (Docket No. FDA–2022–P–2644). In February 2024, the petitioner submitted a potential draft special control guidance document for devices under product code OAY for FDA to consider. FDA also heard from health care practitioners, patients, medical device manufacturers, a patient advocacy organization, and the holder of the NDA for CYSVIEW (hexaminolevulinate hydrochloride) in connection with the Reclassification Petition, who were in favor of reclassifying devices under product code OAY from class III to class II.[12] On March 27, 2026, FDA denied the Reclassification Petition, as FDA did not agree that the information provided and the special controls proposed by the petitioner supported reclassification from class III to class II.

As discussed in this proposed order, FDA is now proposing, on its own initiative, to reclassify cystoscopic systems intended as an aid for detection of bladder cancer from class III to class II. FDA has considered the information available to the Agency and believes that there is sufficient information available to establish special controls and that the special controls proposed in section VII of this document, together with general controls, would provide a reasonable assurance of the safety and effectiveness of devices under product code OAY.

A review of data from FDA's Manufacturer and User Facility Device Experience (MAUDE) database, which contains Medical Device Reports (MDRs) of adverse events, indicates that as of April 30, 2026, there have been 11 unique MDRs associated with product code OAY. Most of the adverse events were related to thermal injury from contact with the light cable. One adverse event was related to user injury, a cut, from a damaged device. Two MDRs reported that the blue light mode stopped working after the first use.

Based on a search of FDA's Medical Device Recalls database using product code OAY, as of June 15, 2026, there has been one recall involving a cystoscopic system intended as an aid for detection of bladder cancer. The recall was initiated by the device manufacturer on August 16, 2012, and was reported to be due to the system's instruction manuals containing a labeling error. The correction applied to the three component manuals indicated for use within the device. To address the labeling error, a Safety Alert letter was sent to all customers to inform them that there was a labeling error, including instructions on how to correct the error. The recall was classified as a class II[13] recall and was terminated by FDA on May 8, 2013.[14] FDA is not aware of any injuries related to this recall. These facts, coupled with the low number of MDRs, indicate a lack of significant postmarket safety signals for this device type. FDA believes the special controls proposed herein, in addition to general controls, can effectively mitigate the risks to health identified in this document to provide a reasonable assurance of the safety and effectiveness of cystoscopic systems intended as an aid for detection of bladder cancer.

III. Device Description

A cystoscopic system intended as an aid for detection of bladder cancer is a postamendments device classified into class III under section 513(f)(1) of the FD&C Act. A cystoscopic system intended as an aid for detection of bladder cancer is a prescription device intended for use with an approved optical imaging agent for photodynamic blue light cystoscopy, as an adjunct to white light cystoscopy for the detection of bladder cancer, including carcinoma in situ, in patients suspected or known to have the lesion on the basis of a prior cystoscopy, or in patients undergoing surveillance cystoscopy for bladder cancer. The device is not intended as the sole or definitive basis for diagnosis. The device system includes a cystoscope and accessories, including a light source, camera system, fluid light cables, and software. The device can be used in white light or blue light modes. The blue light mode is used to view tissue fluorescence, either via the eyepiece on the scope or on a video monitor, after application of an approved optical imaging agent. The optical imaging agent reacts with the bladder lesions to provide visualization under blue light through the cystoscope. As discussed in section VI of this document, tissue fluorescence observation under blue light offers enhanced detection of potential bladder cancer compared to tissue observation under white light.

FDA is proposing to reclassify cystoscopic systems intended as an aid for detection of bladder cancer from class III (premarket approval) to class II (special controls) and to establish a new name for the device type as described within the classification regulations. FDA proposes to revise 21 CFR part 876 to create a new device classification regulation with the name ''Cystoscopic system intended as an aid for detection of bladder cancer.'' The Agency believes that this name and the identification language included in this proposed order more accurately describes this device type.

IV. Proposed Reclassification and Summary of Reasons for Reclassification

In accordance with section 513(f)(3) of the FD&C Act and 21 CFR part 860, subpart C, FDA is proposing to reclassify cystoscopic systems intended as an aid for detection of bladder cancer, which are postamendments devices, from class III into class II, subject to section 510(k) of the FD&C Act.

FDA believes that there is sufficient data and information available to FDA

[12] See Docket No. FDA–2022–P–2644 available at: *https://www.regulations.gov/docket/FDA-2022-P-2644*.

[13] Class I, II, and III recalls are defined in 21 CFR 7.3(m).

[14] For details about termination of a recall, see 21 CFR 7.55.

through the data and information provided in the original PMA (P050027) and one PMA supplement (P050027/S011) for the PDD System that may be considered under section 520(h)(4) of the FD&C Act, the ODAC materials, published peer-reviewed literature, and FDA's publicly available MAUDE and Medical Device Recalls databases to establish special controls (Refs. 3 and 7 to 14). More specifically, in evaluating these data sources, FDA has identified the risks to health for inclusion in the overall risk assessment for a cystoscopic system intended as an aid for detection of bladder cancer and is proposing special controls that include mitigation measures for each of the risks to health identified in section V. FDA believes that these special controls, together with general controls, would effectively mitigate the risks to health identified in section V and are necessary to provide a reasonable assurance of safety and effectiveness of these devices. FDA does not believe that the general controls applicable to the devices are sufficient to effectively mitigate the risks to health identified for these devices, such as the risk of additional biopsies from false positive results or delayed diagnosis due to false negative results and, therefore, does not believe that the general controls applicable to the devices are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

FDA is proposing to revise 21 CFR part 876 to create a new device classification regulation with the name ''Cystoscopic system intended as an aid for detection of bladder cancer.'' Under this proposed order, if finalized, cystoscopic systems intended as an aid for detection of bladder cancer will be identified as prescription devices. If the proposed order is finalized, these devices will be subject to the prescription labeling requirements for devices (see 21 CFR 801.109).

Under the FD&C Act, 510(k) submissions are required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt from 510(k) requirements under section 510(m) of the FD&C Act.[15] FDA has not made this determination for cystoscopic systems intended as an aid for detection of bladder cancer, and therefore FDA is not proposing that these proposed class II devices be exempt from 510(k) requirements. If this proposed order is finalized, persons who intend to market a cystoscopic system intended as an aid for detection of bladder cancer will need to submit a 510(k) to FDA and receive clearance prior to marketing the device.

This proposed order, if finalized, will decrease regulatory burden on industry, as manufacturers will no longer have to submit a PMA for this type of device but can instead submit a 510(k) to the Agency for review prior to marketing their device. The 510(k) pathway is less burdensome and generally more cost-effective for industry and FDA than the PMA pathway, the most stringent type of device marketing pathway. A 510(k) typically results in a shorter premarket review timeline compared to a PMA, which ultimately may provide more timely patient access for this type of device. FDA expects that the reclassification of these devices would enable more manufacturers to develop this type of device such that patients would benefit from increased access to appropriately safe and effective devices used adjunctively to detect bladder cancer.

Additionally, manufacturers may wish to use predetermined change control plans (PCCPs) as a way to implement future modifications to their devices without needing to submit a new 510(k) for each significant change or modification [16] while continuing to provide a reasonable assurance of device safety and effectiveness.[17] FDA reviews a PCCP as part of a marketing submission for a device to ensure the continued safety and effectiveness of the device without necessitating additional marketing submissions for implementing each modification to the device as described in the PCCP. When used appropriately, PCCPs authorized by FDA are expected to be least burdensome for manufacturers and FDA.[18]

[15] See *supra* note 8.

[16] For the purpose of this proposed order, reference to ''modification'' means a significant change or modification that would generally require a new premarket notification under 21 CFR 807.81(a)(3).

[17] Section 3308 of the Food and Drug Omnibus Reform Act of 2022, Title III of Division FF of the Consolidated Appropriations Act, 2023, Public Law 117–328 (FDORA), enacted on December 29, 2022, added section 515C ''Predetermined Change Control Plans for Devices'' to the FD&C Act (21 U.S.C. 360e–4). Section 515C has provisions regarding PCCPs for devices requiring premarket approval or premarket notification. Under section 515C, supplemental applications (section 515C(a)) and new premarket notifications (section 515C(b)) are not required for a change to a device that would otherwise require a premarket approval supplement or new premarket notification if the change is consistent with a PCCP approved or cleared by FDA.

[18] Sections 513 and 515 of the FD&C Act. See also, FDA's guidance titled ''The Least Burdensome Provisions: Concept and Principles,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles.*

V. Risks to Health

FDA is providing a substantive summary of the valid scientific evidence concerning the public health benefits of the use of cystoscopic systems intended as an aid for detection of bladder cancer and the risks to health of these devices (see further discussion of the special controls being proposed to mitigate these risks in section VII of this proposed order). FDA considered data from the original PMA for the PDD System (P050027) and one PMA supplement (P050027/S011) available to FDA under section 520(h)(4) of the FD&C Act, input from the ODAC, published peer-reviewed literature, and postmarket information regarding cystoscopic systems intended as an aid for detection of bladder cancer.

In 2025, the number of new cases of bladder cancer is estimated to have been 84,870, or 4.2 percent of all estimated new cancer cases. The number of deaths in the United States in 2025 from bladder cancer is estimated to have been 17,420, equating to 2.8 percent of all estimated cancer deaths (Ref. 15). Currently, a combination of methods is used for diagnosis of bladder cancer because no single available procedure detects all malignancies. The use of cystoscopic systems intended as an aid for detection of bladder cancer provides a benefit to the public health by improving visualization and identification of malignant lesions of the bladder not detected by white light cystoscopy alone (see discussion in section VI of this document). Use of the device in combination with an approved optical imaging agent can provide a source of adjunctive information when triaging patient care for bladder cancer.

Based on FDA's review of the data and information described in this section and section VI of this document, the Agency has identified the following risks to health associated with the use of cystoscopic systems intended as an aid for detection of bladder cancer:

- *False positive or false negative results*—False negative results could result in complications such as incorrect or delayed diagnoses and delays in biopsy decisions and bladder cancer treatment, which may allow an undetected condition to worsen and potentially increase morbidity and mortality. False positive results may result in complications such as incorrect treatment management of the patient, including unnecessary additional invasive biopsy procedures and more frequent screenings, as well as the potential administration of inappropriate treatments and/or the

delay of appropriate treatments, with possible adverse effects.

- *Device failure/malfunction*—Device failure or malfunction could result in the absence or delay of device output, or incorrect device output, which could lead to inaccurate patient assessment. Inaccurate results may result in the same complications associated with false negative or false positive results as discussed in this section.
- *Electrical, mechanical, thermal, or light-related injury*—While in operation, the device may discharge electricity that could shock the user or patient. Electrical discharge or exposure to device-generated heat may cause thermal injury or discomfort. Moving parts may cause mechanical injury. For devices that utilize energy (*e.g.,* light) to provide adjunctive diagnostic information, accidental eye exposure to the energy source could cause eye injury or high levels of light output could cause photochemical or photothermal tissue damage to the mucosal lining.
- *Interference with other devices*—Individuals with electrically powered implants could experience an adverse interaction with the device due to electromagnetic interference or radiofrequency interference.
- *Infection/Cross contamination*—If reusable components are not adequately reprocessed between uses, the device may introduce pathogenic organisms to patients and cause an infection.
- *Adverse tissue reaction*—A patient could experience skin irritation and/or allergic reaction associated with the use and operation of the device via the use of non-biocompatible materials in patient-contacting devices.

VI. Summary of Data Upon Which the Reclassification Is Based

The safety and effectiveness of this device type have become well established since the initial approval in 2010 of the first cystoscopic system intended as an aid for detection of bladder cancer. FDA believes that cystoscopic systems intended as an aid for detection of bladder cancer, which are used with an approved optical imaging agent and intended as an adjunct to white light cystoscopy for the detection of known or suspected bladder cancer, should be reclassified from class III (premarket approval) into class II (special controls) on the basis that special controls, in addition to general controls, can be established to mitigate the risks to health identified in section V, and there is sufficient information to establish such special controls which, in addition to general controls, would provide a reasonable assurance of the safety and effectiveness of these devices. The proposed special controls are identified by FDA in section VII of this proposed order.

Taking into account the available evidence, including the health benefits of the use of these devices and the nature and known incidence of the risks to health of the devices, FDA, on its own initiative, is proposing to reclassify these postamendments class III devices into class II. FDA has considered and analyzed the following information to support this proposed reclassification: (1) data from the original PMA (P050027) and one PMA supplement (P050027/S011) for the PDD System, including information available in the SSED and device labeling, available to FDA in accordance with section 520(h)(4) of the FD&C Act, (2) input from the ODAC for CYSVIEW (hexaminolevulinate hydrochloride) when used in combination with the PDD System, (3) published peer-reviewed literature, and (4) MDR and recall data from the Agency's publicly available MAUDE and Medical Device Recalls databases. The available evidence demonstrates that there are public health benefits derived from the use of cystoscopic systems intended as an aid for detection of bladder cancer by improving visualization and identification of malignant lesions of the bladder not detected by white light cystoscopy alone. In addition, the nature of the associated risks to health are known, and special controls can be established to sufficiently mitigate these risks.

The data considered by the Agency included the results of non-clinical testing of the PDD System, which demonstrated that the device had acceptable optical performance, electrical safety, electromagnetic compatibility, and reprocessing methods (Ref. 7). The data also included the results of a pivotal clinical trial supporting the use of the PDD System with CYSVIEW (hexaminolevulinate hydrochloride) for photodynamic blue light cystoscopy, as an adjunct to white light cystoscopy, for the detection of non-muscle invasive papillary cancer of the bladder in patients suspected or known to have the lesion on the basis of a prior cystoscopy, which met its primary effectiveness endpoints by exceeding the prespecified 10 percent threshold for patients who had a Ta or T1 lesion detected only with blue light (Ref. 7). FDA also considered data from postmarket clinical trial results supporting the expanded indications of the PDD System for carcinoma in situ and surveillance cystoscopy, which confirmed the increased efficacy of using photodynamic blue light cystoscopy with CYSVIEW (hexaminolevulinate hydrochloride) over white light cystoscopy in detecting non-muscle invasive bladder cancer, including carcinoma in situ (Ref. 8).

The data also included safety data from six studies conducted during clinical development of CYSVIEW (hexaminolevulinate hydrochloride) used in combination with the PDD System, as summarized in the PDD System SSED (Ref. 7). Adverse events included bladder spasm, dysuria, hematuria, bladder pain, procedural pain, urethral pain, urinary retention, headache, erythema, and pruritus (Refs. 7 and 8). These are common complications in patients undergoing cystoscopy procedures, which generally include administration of a general anesthetic, cystoscopy, and biopsy. In addition, concerns raised by the ODAC during its review of CYSVIEW (hexaminolevulinate hydrochloride) when used in combination with the PDD System included concerns about false positives that may lead to unnecessary biopsies, which were relevant to the device, in addition to concerns generally associated with use of the drug (*e.g.,* hypersensitivity, anaphylactic reaction) (Ref. 3).

FDA performed a literature search of published peer-reviewed literature to evaluate the safety and effectiveness of FDA-approved cystoscopic systems intended as an aid for detection of bladder cancer using the optical imaging agent hexaminolevulinate hydrochloride. The most frequent adverse events reported in patients who underwent photodynamic blue light cystoscopy procedures were hematuria, dysuria, bladder spasm, urinary retention, and bladder pain (Refs. 8 to 10).

The literature search results also included studies comparing photodynamic blue light cystoscopy following white light cystoscopy to white light cystoscopy alone in detecting bladder cancer to determine if the use of photodynamic blue light cystoscopy increases the risk of false positive/negatives over existing white light technologies. These comparisons involved assessments of diagnostic accuracy to mitigate the risk of false positives and false negatives. Diagnostic accuracy was assessed via sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Effectiveness outcomes, including recurrence and residual disease, were also assessed in the comparison where data was available.

In comparisons of photodynamic blue light cystoscopy following white light cystoscopy versus white light

cystoscopy alone, the addition of blue light often showed higher rates of tumor detection (Refs. 8 and 10). Photodynamic blue light cystoscopy had improved sensitivity and NPV compared to white light cystoscopy, while white light cystoscopy had improved specificity compared to photodynamic blue light cystoscopy, and PPV was similar between white and blue light cystoscopy (Refs. 11 to 14). The literature did not indicate a significant difference in the proportion of patients experiencing an adverse event between those that underwent photodynamic blue light cystoscopy as an adjunct to white light cystoscopy and those that underwent white light cystoscopy alone (Ref. 9).

FDA did not identify new risks or safety and effectiveness concerns from the published literature that differed from the Agency's findings from the PMA data, ODAC materials, and postmarket safety data.

A search of FDA's publicly available MAUDE database revealed 11 MDRs for product code OAY as of April 30, 2026. These MDRs were reported to be related to user injury from a damaged device, thermal injury or damage from contact with an overheated light cable, and failure of the blue light mode to work after the device's first use.

Finally, a search of FDA's publicly available Medical Device Recalls database for product code OAY through January 5, 2026, revealed one product recall, a class II recall, related to a labeling error that was addressed by the manufacturer. The recall was terminated on May 8, 2013. The lack of other recalls, coupled with the low number of reported adverse events, indicate no significant postmarket safety signals for this device type (see further discussion of the MDR and recall data in section II of this proposed order).

Based on the Agency's review of the information described in this proposed order, FDA has determined that special controls, in addition to general controls, are necessary to provide a reasonable assurance of safety and effectiveness for cystoscopic systems intended as an aid for detection of bladder cancer and that sufficient information exists to establish such special controls. Therefore, FDA, on its own initiative, is proposing to reclassify these postamendments devices from class III (premarket approval) into class II (special controls), subject to 510(k) requirements.

VII. Proposed Special Controls

FDA believes that cystoscopic systems intended as an aid for detection of bladder cancer can be reclassified into class II with the establishment of special controls. FDA believes that the following proposed special controls would mitigate each of the risks to health described in section V and that these special controls, in addition to general controls, would provide a reasonable assurance of safety and effectiveness for cystoscopic systems intended as an aid for detection of bladder cancer. Table 1 demonstrates how FDA believes each risk to health described in section V would be mitigated by the proposed special controls.

To mitigate the risk of false positive and false negative results, FDA believes that clinical data as well as non-clinical performance testing and certain labeling are needed as special controls. Clinical data are needed to demonstrate that the device can provide accurate detection of bladder cancer with appropriate sensitivity and specificity when used with the approved optical imaging agent(s) specified in the device labeling, as a determination of the likelihood of obtaining a false positive or false negative result needs to be confirmed through clinical biopsy samples in patients with known or suspected bladder cancer. This evaluation cannot be replicated in a non-clinical model, and non-clinical performance testing and labeling would not adequately mitigate this risk.

However, in addition to clinical data, non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and must verify and validate filter specifications and functional characteristics, including spectrum and intensity of the illumination source, spectrum of any excitation or emission filters, excitation power and power density, and the optical performance of the cystoscopic system. This non-clinical performance testing would allow flexibility to evaluate appropriate performance based on the characteristics of the subject device without establishing a specific testing requirement that may not be applicable to a particular cystoscopic system intended as an aid for detection of bladder cancer.

In addition, special controls that require in the labeling a summary of clinical data available for the device, a warning that the device should not be used as the only or definitive basis for diagnosis, a statement describing the compatible approved optical imaging agent or agents with the cystoscope, and a detailed summary of the device technical parameters would further mitigate this risk.

The risk of device failure or malfunction can be mitigated by special controls requiring the non-clinical performance testing described above and software verification, validation, and hazard analysis. This risk would be further mitigated by special controls that require the device labeling to include statements related to any device-specific hazards (*e.g.,* foreseeable situations in which the device is likely to fail or not to operate at its expected performance level) and a warning to the user to assess the device for damage prior to use and instructions on determining whether the device has reached the end of its use-life.

The risk of electrical, mechanical, thermal, or light-related hazards leading to patient or user injury or discomfort can be mitigated by special controls that require (1) performance testing that demonstrates electrical, mechanical, thermal, and optical safety; (2) software verification, validation, and hazard analysis; and (3) device labeling that includes instructions on appropriate usage and maintenance of the device, including servicing.

The risk that the device may interfere with other devices due to radiofrequency or electromagnetic interference can be mitigated by a special control requiring performance testing that demonstrates electromagnetic compatibility and device labeling that includes relevant electromagnetic compatibility testing results.

The risks of infection and cross contamination for patient-contacting components can be mitigated by special controls requiring sterilization and reprocessing validation for device components intended to be sterilized by the user prior to use, shelf-life testing, and labeling that includes validated methods and instructions for sterilization and/or reprocessing of any reusable components and an expiration date for any components provided sterile.

The risk of adverse tissue reaction for patient-contacting devices can be mitigated by special controls that require elements of the device that may contact the patient to be demonstrated to be biocompatible and labeling that includes instructions for device maintenance and validated methods and instructions for reprocessing of any reusable components.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR CYSTOSCOPIC SYSTEMS INTENDED AS AN AID FOR DETECTION OF BLADDER CANCER

Identified risks to health	Mitigation measures
False positive or false negative results.	Clinical data Non-clinical performance testing. Labeling.
Device failure or malfunction.	Non-clinical performance testing Software verification, validation, and hazard analysis. Labeling.
Electrical, mechanical, thermal, or light-related injury.	Electrical, mechanical, thermal, and optical safety testing Software verification, validation, and hazard analysis. Labeling.
Interference with other devices.	Electromagnetic compatibility testing. Labeling.
Infection and cross contamination.	Sterilization/reprocessing validation. Shelf-life testing Labeling.
Adverse tissue reaction.	Biocompatibility evaluation. Labeling.

If this proposed order is finalized, cystoscopic systems intended as an aid for detection of bladder cancer will be identified as prescription devices. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act and 21 CFR 801.5 if the conditions of 21 CFR 801.109 are met.

If this proposed order is finalized, cystoscopic systems intended as an aid for detection of bladder cancer will be reclassified into class II (special controls) and will be subject to premarket notification requirements under section 510(k) of the FD&C Act. As discussed in this proposed order, the intent is for the reclassification to be codified in the new classification regulation 21 CFR 876.1560. If finalized, firms will be required to comply with the particular mitigation measures set forth in the special controls. FDA believes that adherence to the special controls, in addition to the general controls, is necessary to provide a reasonable assurance of the safety and effectiveness of cystoscopic systems intended as an aid for detection of bladder cancer.

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

While this proposed order contains no new collections of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 820 (Quality Management System Regulation) have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 807, subpart E (Premarket Notification Procedures) have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 801 (Device Labeling) have been approved under OMB control number 0910–0485, and the collections of information in 21 CFR part 814 (Premarket Approval of Medical Devices) have been approved under OMB control number 0910–0231.

X. Proposed Effective Date

FDA proposes that any final order based on this proposed order become effective 30 days after the date of its publication in the **Federal Register**.

XI. Codification of Orders

Under section 513(f)(3) of the FD&C Act, FDA may issue final orders to reclassify devices. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as newly codified orders. Therefore, under section 513(f)(3) of the FD&C Act, in the proposed order, we are proposing to codify ''Cystoscopic system intended as an aid for detection of bladder cancer'' in the new 21 CFR 876.1560, under which these cystoscopic systems intended as an aid for detection of bladder cancer would be reclassified from class III into class II.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

* 1. FDA, PMA No. P050027, Approval Order (May 28, 2010). Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P050027.*
* 2. PMA No. P050027, Approved Labeling at p. 7. Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P050027.*
* 3. FDA, December 17, 2009, Meeting of the Oncologic Drugs Advisory Committee, Transcript. Available at *https://www.fda.gov/advisory-committees/human-drug-advisory-committees/oncologic-drugs-advisory-committee.*
* 4. FDA, Supplemental NDA 22555/S–005 Approval Letter (February 15, 2018). Available at *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/022555Orig1s005ltr.pdf.*
* 5. FDA, Center for Devices and Radiological Health, ''2014–2015 Strategic Priorities.''
* 6. FDA, First Cohort of Results of the 2014–2015 Strategic Priority: Strike the Right Balance Between Premarket and Postmarket Data Collection (April 2015). Available at *https://wayback.archive-it.org/7993/20161022062758/http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM444804.pdf.*
* 7. FDA, PMA No. P050027, Summary of Safety and Effectiveness. Available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P050027.*
8. Daneshmand, S., S. Patel, Y. Lotan, et al. ''Efficacy and Safety of Blue Light Flexible Cystoscopy with Hexaminolevulinate in the Surveillance of Bladder Cancer: A Phase III, Comparative, Multicenter Study,'' *Journal of Urology,* 199(5):1158–1165, May 2018. doi:10.1016/j.juro.2017.11.096. Available at *https://pubmed.ncbi.nlm.nih.gov/29203268.*
9. Stenzl, A., M. Burger, Y. Fradet, et al. ''Hexaminolevulinate-Guided Fluorescence Cystoscopy Reduces Recurrence in Patients with Non-muscle Invasive Bladder Cancer,'' *Journal of Urology,* 184(5):1907–13, November 2010. doi:10.1016/j.juro.2010.06.148. Available at *https://pmc.ncbi.nlm.nih.gov/articles/PMC4327891.*
10. Palou, J., C. Hernández, E. Solsona, et al. ''Effectiveness of Hexaminolevulinate Fluorescence Cystoscopy for the Diagnosis of Non-Muscle-Invasive

Bladder Cancer in Daily Clinical Practice: A Spanish Multicentre Observational Study,'' *BJU International,* 116(1):37–43 July 2015. doi:10.1111/bju.13020. Available at *https://bjui-journals.onlinelibrary.wiley.com/doi/10.1111/bju.13020.*

11. Ladi-Seyedian, S.S., A. Ghoreifi, B. Konety, et al. ''Racial Differences in the Detection Rate of Bladder Cancer Using Blue Light Cystoscopy: Insights from a Multicenter Registry,'' *Cancers,* 16(7), 2024. doi:10.3390/cancers16071268. Available at *https://pmc.ncbi.nlm.nih.gov/articles/PMC11011163.*
12. Ray, E.R., K. Chatterton, M.S. Khan, et al. ''Hexylaminolaevulinate Fluorescence Cystoscopy in Patients Previously Treated with Intravesical Bacille Calmette-Guérin,'' *BJU International,* 105(6):789–94, March 2010. doi:10.1111/j.1464–410X.2009.08839.x. Available at *https://bjui-journals.onlinelibrary.wiley.com/doi/10.1111/j.1464-410X.2009.08839.x.*
13. Drăgoescu, P.O., Ş. Tudorache, A.I. Drocaş, et al. ''Improved Diagnosis and Long-Term Recurrence Rate Reduction for Non-Muscle-Invasive Bladder Cancer Patients Undergoing Fluorescent Hexylaminolevulinate Photodynamic Diagnosis,'' *Romanian Journal of Morphology and Embryology,* 58(4):1279–1283, 2017. Available at *https://www.rjme.ro/RJME/resources/files/Dragoescu_Petru_Octavian_RJME_58_4_2017.pdf.*
14. Lee, J.S., S.Y. Lee, W.J. Kim, et al. ''Efficacy and Safety of Hexaminolevulinate Fluorescence Cystoscopy in the Diagnosis of Bladder Cancer,'' *Korean Journal of Urology,* 53(12):821–825, December 2012. doi:10.4111/kju.2012.53.12.821. Available at *https://pmc.ncbi.nlm.nih.gov/articles/PMC3531633.*
* 15. National Cancer Institute, ''Cancer Stat Facts: Bladder Cancer.'' Available at *https://seer.cancer.gov/statfacts/html/urinb.html.* Accessed on January 20, 2026).

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 876 be amended as follows:

PART 876—GASTROENTEROLOGY–UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 876.1560 to subpart B to read as follows:

§ 876.1560 Cystoscopic system intended as an aid for detection of bladder cancer.

(a) *Identification.* A cystoscopic system intended as an aid for detection of bladder cancer is a prescription device, which includes a cystoscope and accessories, intended for use with an approved optical imaging agent for photodynamic blue light cystoscopy as an adjunct to white light cystoscopy for the detection of known or suspected bladder cancer, including carcinoma in situ, or in patients undergoing surveillance cystoscopy for bladder cancer. The device is not intended to be the sole or definitive basis for diagnosis.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical data must confirm accurate detection of bladder cancer when used with the approved optical imaging agent(s) specified in the device labeling based on output from the device including an assessment of appropriate sensitivity and specificity.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, and must verify and validate filter specifications and functional characteristics including the following:

(i) Spectrum and intensity of the illumination source;

(ii) Spectrum of any excitation or emission filters;

(iii) Excitation power and power density; and

(iv) Optical performance of the cystoscopic system.

(3) Performance testing must demonstrate electromagnetic compatibility and electrical, mechanical, thermal, and optical safety of the device.

(4) The patient-contacting components of the device must be demonstrated to be biocompatible.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Performance data must demonstrate the sterility of the device or device components intended to be provided sterile.

(7) Performance data must validate the reprocessing instructions for reusable components of the device.

(8) Performance data must support the shelf life of the device or device components intended to be provided sterile by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(9) Labeling must include the following:

(i) A detailed summary of the device technical parameters.

(ii) An expiration date for the device or device components provided sterile.

(iii) Summary of clinical data available for the device.

(iv) A warning that the device should not be used as the only or definitive basis for diagnosis.

(v) A statement describing the approved optical imaging agent(s) that are compatible for use with the cystoscope and supported by the clinical data described in (b)(1).

(vi) Where components are intended to be sterilized by the user prior to initial use and/or are reusable, validated methods and instructions for sterilization and reprocessing, as applicable, of any reusable components.

(vii) Statements related to any device specific hazards (*e.g.,* foreseeable situations in which the device is likely to fail or not to operate at its expected performance level).

(viii) A warning to assess the device for damage prior to use and instructions on determining whether the device has reached the end of its use-life.

(ix) Instructions on appropriate usage and maintenance of the device, including relevant electromagnetic compatibility testing results and servicing.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16728 Filed 8–14–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–109082–25]

RIN 1545–BR58

Proposed Removal of a Reporting Requirement for Trusts Whose Charitable Contribution Deductions Are Solely for Contributions Made by Passthrough Entities

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that would amend existing regulations that require certain trusts to report all charitable contributions and amounts permanently set aside for a charitable purpose on Form 1041–A, *U.S. Information Return Trust Accumulation of Charitable Amounts.* The proposed regulations would remove the reporting requirement for these trusts with respect to taxable years in which the trust's only claimed charitable contribution deduction results from charitable