The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it received on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov* as described in the system of records notice (DOT/ALL–14FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address, phone number, and hours of operation). An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Incorporation by Reference

Class E airspace is published in paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11K, dated August 4, 2025, and effective September 15, 2025. These updates would be published subsequently in the next update to FAA Order JO 7400.11. FAA Order JO 7400.11K, which lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points, is publicly available as listed in the **ADDRESSES** section of this document.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 that would establish Class E airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Northwestern Memorial Healthcare Heliport, DeKalb, IL.

This action is the result of instrument procedures being developed for this airport to support IFR operations.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Order 2100.6B, ''Policies and Procedures for Rulemakings'' (March 10, 2025); and (3) is expected to result in, at most, de minimis costs from compliance with applicable operating requirements or minor flight rerouting for operators choosing to navigate around the controlled airspace. Since these proposed amendments are routine and the expected impact to operators is de minimis, the FAA certifies that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1G, ''FAA National Environmental Policy Act Implementing Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11K, Airspace Designations and Reporting Points, dated August 4, 2025, and effective September 15, 2025, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth

* * * * *

AGL IL E5 DeKalb, IL [Establish]

Northwestern Memorial Healthcare Heliport, IL
(Lat. 41°57′38″ N., long. 88°43′18″ W.)
That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Northwestern Memorial Healthcare Heliport.

* * * * *

Issued in Fort Worth, Texas, on August 13, 2026.

Jerry J. Creecy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2026–16750 Filed 8–14–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 870, 876, and 878

[Docket No. FDA–2025–N–6224]

Medical Devices; Classification of Accessories Distinct From Other Devices; Proposed List of Accessories Suitable for Class I; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; request for comments.

SUMMARY: As required by the FDA Reauthorization Act of 2017 (FDARA), the Food and Drug Administration (FDA or Agency) has identified a list of accessories for which the Agency believes general controls alone are sufficient to provide reasonable assurance of safety and effectiveness, making them appropriate for class I classification. FDA is publishing this document proposing to classify these accessories into class I and distinct from other devices, as well as seeking public comment in accordance with procedures established by FDARA. This document does not represent FDA's final determination with respect to the proposed accessories listed in this document.

DATES: Either electronic or written comments on the notification must be submitted by October 16, 2026.

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–2025–N–6224 for ''Medical Devices; Classification of Accessories Distinct from Other Devices; Proposed List of Accessories Suitable for Class I; Request for Comments.'' 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.'' The Agency 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 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: Ian Ostermiller, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5454, Silver Spring, MD 20993–0002, 301–796–5678.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act) sets forth a process to classify certain medical devices, *i.e.,* accessories, separate from the parent device or system of devices with which the accessory is intended to be used. FDA refers to this process as distinct classification, and it originates from section 707 of FDARA, which was signed into law on August 18, 2017 (131 Stat. 1060–62, Pub. L. 115–52). Under section 513(f)(6)(D)(i) of the FD&C Act as amended by FDARA (21 U.S.C. 360c(f)(6)(D)(i)), FDA periodically proposes accessories that may be suitable for distinct classification into class I and seeks public comment on the proposal. This notification is a periodic proposal pursuant to section 513(f)(6)(D)(i) of the FD&C Act, and FDA is seeking feedback on this proposal through public comment. This notification follows a request for public input regarding which accessories to consider proposing for distinct classification that FDA posted on its website on December 5, 2025, to develop this document.[1]

II. Legal Authority

The accessories subject to this proposal are devices regulated under the FD&C Act. Specifically, section 201(h) of the FD&C Act defines a ''device'' to include, among other articles, an ''accessory'' (see 21 U.S.C. 321(h)). An accessory is a kind of device, and all articles that meet the definition of ''device'' are regulated under the FD&C Act. FDA has described our current thinking on which devices FDA would generally consider to be accessories in the guidance document, ''Medical Device Accessories—Describing Accessories and Classification Pathways''(''Accessories Guidance'').[2] That guidance, based on sections 201(h) and 513(f)(6) of the FD&C Act, defines an accessory as a ''finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices.''

FDA regulates devices according to classes that reflect the regulatory controls necessary to provide reasonable assurance of their safety and effectiveness. Section 513 of the FD&C Act defines three classes of devices, which are class I (general controls), class II (special controls), and class III (premarket approval). Because accessories may have marketing

[1] Available at *https://www.fda.gov/medical-devices/classify-your-medical-device/cdrh-seeks-public-comment-identifying-accessories-suitable-distinct-classification-class-i-devices.* A copy is also available in the public docket. FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

[2] Available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429672.*

authorization as part of a submission for another device with which they are intended to be used, often called the parent device or system of devices, an accessory may be subject to more than general controls on account of the parent device or system of devices. However, for some such accessories, general controls alone may suffice to provide reasonable assurance of safety and effectiveness when the accessory is considered distinct from the parent device or system of devices.

General controls, under section 513(h)(1) of the FD&C Act, are the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520 of the FD&C Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j). These controls include, but are not limited to, provisions related to adulteration and misbranding, registration and listing, records and reports on devices, and good manufacturing practices. The provisions for good manufacturing practices under 21 CFR part 820, the Quality Management System Regulation, include requirements for design and development controls for the manufacture of certain devices. However, requirements for design and development controls generally do not apply to class I devices except those identified in § 820.10(c)(2) (21 CFR 820.10(c)(2)) and those automated with computer software.

FDA is publishing this document pursuant to the legal authorities discussed in this notification and providing the public with the opportunity to comment on the proposals. Once the comment period ends, FDA will consider the comments and publish in the **Federal Register** a final action distinctly classifying suitable accessories into class I, if any.

III. Factors for Consideration

The classification of each accessory will be based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used (see section 513(f)(6)(A) of the FD&C Act).

In general, FDA considers an accessory to be eligible for classification into class I distinct from another device if the accessory: (1) is not for use in supporting or sustaining human life, or of substantial importance in preventing impairment to human health (see 21 CFR 860.3, defining ''life-supporting or life-sustaining device,'' among other terms); (2) does not present a potential unreasonable risk of illness or injury; and (3) general controls alone would be sufficient to provide a reasonable assurance of safety and effectiveness of the accessory.

Note that by regulation, design and development controls apply to class I devices only if the devices are automated with computer software or are listed under § 820.10(c)(2). Thus, if an accessory is not automated with computer software but would require design controls to provide reasonable assurance of safety and effectiveness, FDA does not consider it eligible for distinct classification through this process.

Similarly, ''device-specific accessories'' are accessories designed for use with a specific parent device and/or system of devices, based upon unique dimensions, geometry, and/or deployment. In these cases, design specifications are critical to the proper use of the accessory in supporting, supplementing, and/or augmenting the performance of the parent device and/or the specific system. For such device-specific accessories, design and development controls are an important element of ensuring appropriate compatibility between the accessory and parent and/or system, and as such, device-specific accessories are not generally eligible for distinct classification through this process. In the **Federal Register** of August 17, 2018, FDA proposed this rationale for device-specific orthopedic instruments (83 FR 41023, 41025–26), which we then adopted in the **Federal Register** of April 12, 2019 (84 FR 14865, 14869). The same principle and definition apply to this proposal.

You may wish to propose additional accessories as suitable for distinct classification into class I using the factors described above where the accessories are otherwise eligible for classification under section 513(f)(6)(D)(i) of the FD&C Act. Should you wish to propose additional accessories, your comment should identify each accessory's product code and/or classification regulation, and it should briefly explain why you think general controls alone will provide reasonable assurance of safety and effectiveness for the accessory if distinctly classified.[3] Conversely, should you disagree with any of the proposed accessories for class I, your comments should briefly explain why additional regulatory controls, such as premarket review through a 510(k) submission or premarket approval (PMA), are necessary to provide reasonable assurance of safety and effectiveness.

IV. Proposed List of Accessories for Distinct Classification Into Class I

FDA is proposing the following accessories, which have been granted marketing authorization as part of a premarket submission (*i.e.,* 510(k), De Novo classification request, or PMA) for another device with which they are intended to be used, as suitable for distinct classification into class I (see table 1). When FDA publishes the final list of accessories, after considering comments submitted for this proposed list and the factors in section II, FDA will consider those accessories classified into class I, distinct from other devices, through such action.

For each distinct classification that is finalized as proposed, FDA would place a classification regulation for each of these accessories in 21 CFR part 870, 876, or 878, as appropriate. Each of these accessories would be class I, exempt from the premarket notification procedures in 21 CFR part 807, subject to the applicable limitations of exemption (*i.e.,* 21 CFR 870.9, 876.9, or 878.9). FDA intends to make conforming changes to existing classification regulations for consistency and clarity, as appropriate.

[3] FDA's Product Classification Database for medical devices is online at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.*

TABLE 1—PROPOSED ACCESSORIES FOR CLASSIFICATION INTO CLASS I AND DISTINCT FROM OTHER DEVICES

Current classification regulation (21 CFR)	Device type (existing product code)	Proposed device type identification
	Current Status of Accessory	
870.1130	Noninvasive blood pressure measurement system accessories (DXN).	A tube connecting the blood pressure cuffs to the noninvasive blood pressure measurement system.
870.3610	Electrocardiogram cable (DXY and OSR).	Implantable pacemaker pulse electrocardiogram cable accessories are cables used to transmit electrical signals between a pacing device and cardiac pacing leads or to connect the implantable pacemaker pulse generator system to compatible external equipment. They are not intended to power the implant or transmit energy to the implant.
870.4100	Extracorporeal membrane oxygenation accessories (QJZ and QNR).	A non-electrical device that has no contact with blood and that is used in an extracorporeal membrane oxygenation circuit to support, adjoin, or connect components, or to aid in the setup of the extracorporeal line. Examples include but are not limited to an oxygenator mounting bracket or system-priming equipment. It is not intended to be used in transport environments.
870.5300	Auxiliary power supply (alternating current or direct current) for low-energy direct-current defibrillator (MPD).	An accessory used to charge the defibrillator batteries when the defibrillator is not in use.
876.5130	Urological catheter plug (KNY).	Sterile plug used with a urological catheter to seal the distal end of the catheter to prevent contamination of the catheter and/or leakage of urine from the catheter.
878.4400	Detachable suction sleeve (GEI).	Detachable plastic attachment at the distal end of a smoke evacuating monopolar pencil that channels surgical smoke away from the surgical site. It is a single-use and sterile device.
878.4740 878.4750	Power charger accessory to a battery-powered surgical instrument (GAG and GDW).	An accessory used to supply an electrical charge to the battery.

In addition, FDA received comments in response to the December 2025 request posted on our website suggesting that FDA distinctly classify reprocessing aids or tools, as well as percutaneous catheterization accessories. However, the suggestions did not identify product codes or classification regulations. Further, FDA has not separately identified such devices suitable for distinct classification. Information submitted in response to this notification that describes devices by referring to specific product codes may facilitate the identification and potential distinct classification into class I for such accessories.

V. Paperwork Reduction Act of 1995

While this document contains no new collection of information, it does refer to previously approved 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 (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR Part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
"De Novo Classification Process (Evaluation of Automatic Class III Designation)".	De Novo classification process	0910–0844
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality Management System Regulation (QMSR).	0910–0073
"Medical Device Accessories—Describing Accessories and Classification Pathways for New Accessory Types.".	Medical Device Accessories	0910–0823

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16729 Filed 8–14–26; 8:45 am]

BILLING CODE 4164–01–P

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