

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

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

■ 2. Add § 878.1830 to subpart B to read as follows:

§ 878.1830 Software-aided adjunctive diagnostic device for use by physicians on lesions suspicious for skin cancer.

(a) *Identification.* A software-aided adjunctive diagnostic device for use by physicians on lesions suspicious for skin cancer is a prescription device that uses a software algorithm to analyze optical or other physical properties of a skin lesion and returns a classification of the skin lesion. The device is intended for use by a physician not trained in the clinical diagnosis and management of skin cancer as an adjunctive second-read device following identification of a suspicious skin lesion. It is not for use as a standalone diagnostic and is not for use to confirm a clinical diagnosis.

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

(1) Data obtained from premarket clinical performance validation testing and postmarket surveillance acquired under anticipated conditions of use must demonstrate that the device performs as intended in the intended patient population, unless FDA determines based on the totality of the information provided for premarket review that data from postmarket surveillance is not required.

(i) Data must demonstrate superior accuracy of device-aided users' diagnostic characterization of the indicated lesions compared to the accuracy of unaided users.

(ii) Clinical testing must evaluate patients across a range of skin phototypes, risk factors, and anatomic areas that represents the intended use population.

(iii) Standalone device performance testing must demonstrate the accuracy of the device output relative to ground truth, including the following:

(A) Testing must demonstrate at least 90 percent sensitivity of the device output for lesions with high metastatic potential, or an alternative clinical consideration must be provided to justify lower sensitivity. Clinical justification must be provided for the reported specificity.

(B) Lesions must be selected by representative users and include a justified quantity and range of mimic lesions per diagnosis.

(C) Justification must be provided for the determination of ground truth.

(D) Testing must include a representative range of individuals with diverse risk factors (including age, body site, skin phototype, and other clinical factors), and analysis of standalone performance must include subgroup analysis by relevant risk factors.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including compatibility testing of the device software with specific signal or image acquisition hardware. Testing must include a description of compatible hardware and processes, pre-specified compatibility testing protocols, and dataset(s).

(3) Performance testing must demonstrate device precision, including repeatability and reproducibility of device performance, across operators and challenging use conditions.

(4) Performance testing must demonstrate the electrical safety, mechanical safety, thermal safety, and electromagnetic compatibility of any electrical components of the device.

(5) Performance testing must validate reprocessing instructions for reusable components of the device.

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

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

(8) Human factors assessment must demonstrate that the device can be safely and correctly used by intended users.

(9) Labeling must include:

(i) A summary of standalone and clinical performance testing conducted with the device that describes performance measures, including sensitivity and specificity, and statistical confidence intervals, as well as performance of the device for all clinically relevant subgroups within the intended use population;

(ii) A description of the patient population that was used in development or training of the device algorithm;

(iii) Device limitations or subpopulations for which the device may not perform as expected or for whom the device has not been validated;

(iv) Information for interpretation of the device outputs detailing the risks associated with misinterpretation of the device outputs;

(v) Warnings to avoid unsafe exposure to any energy-emitting components of the device, *e.g.*, excluding lesions close to the eye;

(vi) A statement that the device is not intended for use as a standalone diagnostic; and

(vii) Instructions for device maintenance and validated methods and instructions for reprocessing of any reusable components.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–22179 Filed 10–29–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. FDA–2026–N–12254]

Medical Devices; Radiology Devices; Classification of the Radiology Software for Referral of Findings Related to Fibrotic Lung Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the radiology software for referral of findings related to fibrotic lung disease into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the radiology software for referral of findings related to fibrotic lung disease. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 30, 2026. The classification was applicable on January 12, 2024.

FOR FURTHER INFORMATION CONTACT: Jessica Lamb, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3672, Silver Spring, MD 20993–0002, 301–796–6167, Jessica.Lamb@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the radiology software for referral of findings related to fibrotic lung disease into class II (special controls), which we have determined

will provide a reasonable assurance of the safety and effectiveness of the device. In addition, we believe this action will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food

and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining “substantial equivalence”). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On June 29, 2022, FDA received Imvaria, Inc.’s request for De Novo classification of the Fibresolve device. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on January 12, 2024, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 892.2085.¹ We have named the generic type of device “radiology software for referral of findings related to fibrotic lung disease,” and it is identified as a prescription image processing device that analyzes computed tomography images to suggest the presence of disease or of an imaging finding suggestive of disease. The output of this device is intended to be used as adjunctive information as part of a referral pathway in the overall diagnostic assessment process.

FDA has identified the risks to health associated with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR RADIOLOGY SOFTWARE FOR REFERRAL OF FINDINGS RELATED TO FIBROTIC LUNG DISEASE

Identified risks to health	Mitigation measures
False positive findings leading to harmful incorrect and/or delayed management of a patient with an alternative underlying fibrotic lung disease.	Clinical performance testing; Postmarket surveillance; and Labeling.
False negative findings leading to harmful incorrect and/or delayed management of a patient with a fibrotic lung disease.	Clinical performance testing; Postmarket surveillance; and Labeling.

¹ FDA notes that the “ACTION” caption for this final order is styled as “Final amendment; final order,” rather than “Final order.” Beginning in December 2019, this editorial change was made to

indicate that the document “amends” the Code of Federal Regulations. The change was made in accordance with the Office of 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.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR RADIOLOGY SOFTWARE FOR REFERRAL OF FINDINGS RELATED TO FIBROTIC LUNG DISEASE—Continued

Identified risks to health	Mitigation measures
Incorrect and/or delayed patient management due to the device being misused to analyze images from an unintended patient population or from images acquired with incompatible imaging hardware or image acquisition parameters.	Clinical performance testing; Postmarket surveillance; and Labeling.
Incorrect and/or delayed patient management due to misinterpretation of device output or overreliance on device output for radiological image interpretation.	Labeling.
Device failure leading to the absence of results, delay of results, or incorrect results, leading to inaccurate or delayed patient assessment.	Software verification, validation, and hazard analysis.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

At the time of classification, radiology software for referral of findings related to fibrotic lung disease are for prescription use only. 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 (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for radiology software for referral of findings related to fibrotic lung disease. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These 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 part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 892 is amended as follows:

PART 892—RADIOLOGY DEVICES

■ 1. The authority citation for part 892 continues to read as follows:

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

■ 2. Add § 892.2085 to subpart B to read as follows:

§ 892.2085 Radiology software for referral of findings related to fibrotic lung disease.

(a) *Identification.* Radiology software for referral of findings related to fibrotic lung disease is a prescription image processing device that analyzes computed tomography images to suggest the presence of disease or of an imaging finding suggestive of disease. The

output of this device is intended to be used as adjunctive information as part of a referral pathway in the overall diagnostic assessment process.

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

(1) Data obtained from premarket clinical performance validation testing and postmarket surveillance acquired under anticipated conditions of use must demonstrate that the device performs as intended when used to analyze data from the intended patient population, unless FDA determines based on the totality of the information provided for premarket review that data from postmarket surveillance is not required. The following must be met:

(i) Validation report(s) must include a detailed description of the data, criteria, and methods used to define the reference standard that were used to evaluate device performance. The reference standard used in the clinical validation must be justified for the condition named in the device's indications for use.

(ii) The performance of the device must be compared to an appropriate clinical control, (e.g., the performance or agreement of clinicians performing the same task).

(iii) The performance assessment must be based on pre-specified diagnostic accuracy measures (e.g., receiver operator characteristic plot, sensitivity, specificity, positive/negative predictive values, diagnostic likelihood ratios).

(iv) Test datasets must contain a sufficient number of cases from important cohorts (i.e., subsets defined by clinically relevant demographics, confounders, effect modifiers, concomitant diseases, challenging cases such as early disease, and subsets defined by image acquisition characteristics) such that the performance estimates and confidence intervals of the device for these individual subsets can be characterized

for the intended-use population and imaging equipment.

(2) Software verification, validation, and hazard analysis must be performed. Software documentation must include a detailed technical description of all image analysis algorithms, including the model inputs and outputs, each major component or block, and any model limitations.

(3) Labeling must include:

(i) A detailed description of the clinical environment and context of use, including information on interpretation of outputs within the intended workflow;

(ii) A detailed description of compatible imaging hardware and imaging protocols;

(iii) A detailed summary of the performance testing for each device output, including test methods, dataset characteristics, testing environment, results (with confidence intervals), and a summary of sub-analyses on case distributions stratified by relevant confounders;

(iv) According to the timeframe specified in any postmarket surveillance protocol approved by FDA to satisfy the requirements in paragraph (b)(1) of this section, a detailed summary of the postmarket surveillance data must be provided, including updates to the labeling to accurately reflect device performance based upon data collected during the postmarket surveillance experience; and

(v) Limiting statements that indicate:

(A) A description of situations in which the device may fail or may not operate at its expected performance level (e.g., the impact of poor image quality on device performance or degraded performance in certain subpopulations), as applicable, including any limitations in the dataset used to train, tune, and test the algorithm during device development;

(B) A discussion of what the device detects in the context of diagnosing fibrotic lung disease; and

(C) A warning that users should use the device in conjunction with other clinical and diagnostic findings, including information obtained by alternative methods and clinical evaluation, as appropriate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-22180 Filed 10-29-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-1743]

Schedules of Controlled Substances: Placement of Centanafadine in Schedule III

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule; request for comments.

SUMMARY: On July 24, 2026, the United States Food and Drug Administration (FDA) approved a new drug application for Simtriyo (centanafadine) for the treatment of attention-deficit/hyperactivity disorder in adults and pediatric patients aged 6 years and older, weighing at least 20 kg. The Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place centanafadine, chemically known as (1R,5S)-1-(naphthalen-2-yl)-3-azabicyclo[3.1.0]hexane, in schedule III of the Controlled Substances Act (CSA). In accordance with the CSA, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing centanafadine, including its salts, isomers (whether optical, positional, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible in schedule III of the CSA.

DATES: This rule is effective October 30, 2026. Comments must be submitted electronically or postmarked on or before November 30, 2026. The electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing, together with a written statement of position on the matters of fact and law asserted in the hearing, must be received on or before November 30, 2026.

ADDRESSES: Interested persons may file written comments on this rulemaking in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.43(g). To ensure proper handling of comments, please reference “Docket No. DEA-1743” on all correspondence, including any attachments.

• *Electronic comments:* The Drug Enforcement Administration (DEA)

encourages commenters to submit comments electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

• *Paper comments:* Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA **Federal Register** Representative/DPW, 8701 Morrisette Drive, Springfield, VA 22152.

• *Hearing requests:* All requests for hearing and waivers of participation, together with a written statement of position on the matters of fact and law asserted in the hearing, must be filed with the DEA Administrator, who will make the determination of whether a hearing will be needed to address such matters of fact and law in the rulemaking. Such requests must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrisette Drive, Springfield, Virginia 22152. For informational purposes, a courtesy copy of requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA **Federal Register** Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

• *Paperwork Reduction Act comments:* All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to Docket No. DEA-1743.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control