Rules and Regulations

Federal Register
Vol. 91, No. 83
Thursday, April 30, 2026

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2025–1183; Airspace Docket No. 25–ASO–12]

RIN 2120–AA66

Amendment of Class E Airspace; Miami, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects a final rule published by the FAA in the **Federal Register** on February 13, 2026, amending Class D and E airspace in Miami, FL. This action corrects discrepancies between the discussion of the rule in the preamble, which contained the accurate airspace description for the Class E airspace for Miami Executive, and the legal description, which failed to implement the changes.

DATES: The effective date of the final rule published in the **Federal Register** on February 13, 2026, remains 0901 UTC, July 9, 2026. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Rachel Cruz, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Ave., College Park, GA 30337; Telephone (404) 305–5571.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule for Docket No. FAA–2025–1183 (91 FR 6751; February 13, 2026), amending Class D and E airspace at Miami, FL. After publication, the FAA discovered that, although the preamble accurately discussed the changes to the Class E airspace, the airspace description did not correctly implement those changes. This action corrects that error. Additionally, the FAA failed to explain the basis for an administrative change that was implemented via the final rule published on February 13, 2026. Specifically, in the final rule, the FAA updated the affected airspace legal description titles to remove the airport name. This was done to comply with the naming conventions in FAA Order JO 7400.2R. No correction is needed because this change was correctly implemented despite the FAA's failure to provide an explanation.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the final rule for Docket No. FAA–2025–1183, as published in the **Federal Register** on February 13, 2026 (91 FR 6751; FR Doc. 2026–02919), is corrected as follows:

■ 1. On page 6752, in the second column, delete the text of the legal description titled, ''ASO FL E2 Miami, FL [Amended],'' and replace it with:

ASO FL E2 Miami, FL [Amended]

Miami Executive Airport, FL
(Lat. 25°38′51″ N, long. 80°26′00″ W)

That airspace extending upward from the surface to and including 2,500 feet MSL within a 4.3-mile radius of the Miami Executive Airport, and within 1.2 miles each side of the 267 bearing from the airport reference point extending from the 4.3-mile radius to 5.9 miles west of the airport reference point, excluding that airspace within the Miami, FL, Class B surface area. This Class E airspace is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Issued in College Park, Georgia, on April 28, 2026.

Patrick Young,

Manager, Airspace & Procedures Team North, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2026–08464 Filed 4–29–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2026–N–3946]

Medical Devices; Cardiovascular Devices; Classification of the Laser-Powered Inferior Vena Cava Filter Retrieval Catheter

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the laser-powered inferior vena cava filter retrieval catheter 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 laser-powered inferior vena cava filter retrieval catheter. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of 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 April 30, 2026. The classification was applicable on December 21, 2021.

FOR FURTHER INFORMATION CONTACT: Brian Pullin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2112, Silver Spring, MD 20993–0002, 301–796–6455, *Brian.Pullin@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the laser-powered inferior vena cava filter retrieval catheter into class II (special controls), which we have determined will provide a reasonable assurance of 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 25, 2021, FDA received Spectranetics, Inc.'s request for De Novo classification of the CavaClear Laser Sheath. 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 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 December 21, 2021, 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 870.5125.[1] We have named the generic type of device ''laser-powered inferior vena cava (IVC) filter retrieval catheter,'' and it is identified as percutaneous catheter that uses a laser to ablate tissue and is intended to facilitate in the detachment and removal of indwelling IVC filters.

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 LASER-POWERED INFERIOR VENA CAVA FILTER RETRIEVAL CATHETER RISKS AND MITIGATION MEASURES

Identified Risks to Health	Mitigation Measures
Infection	Sterilization validation; Shelf life testing; Pyrogenicity testing; and Labeling.
Adverse tissue reaction	Biocompatibility evaluation.
Device damage during use resulting in clinical sequelae such as embolic concern or prolonged procedure.	Non-clinical performance testing; and Clinical performance testing.
Soft tissue damage from laser, such as IVC injury, extravasation, and perforation.	Laser generator compatibility testing; *In-vivo* safety testing; Clinical performance testing; Labeling; and Training.
IVC filter damage, including fracture and embolization, due to laser interaction.	Non-clinical performance testing; Clinical testing; Labeling; and Training.

[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.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of 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.

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 laser-powered inferior vena cava filter retrieval catheters. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has 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 870

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 870 is amended as follows:

PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for part 870 continues to read as follows:

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

■ 2. Add § 870.5125 to subpart F to read as follows:

§ 870.5125 Laser-powered inferior vena cava filter retrieval catheter.

(a) *Identification.* A laser-powered inferior vena cava (IVC) filter retrieval catheter is a percutaneous catheter that uses a laser to ablate tissue and is intended to facilitate in the detachment and removal of indwelling IVC filters.

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

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include:

(i) Evaluation of major and minor complications associated with IVC filter removal; and

(ii) Evaluation of success rates of IVC filter removal.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be evaluated:

(i) Dimensional testing must demonstrate that the device is compatible with the intended anatomy and compatible with all labeled accessories.

(ii) Mechanical testing on all joints must demonstrate that the device can withstand tensile and torsional forces encountered under challenging clinical use conditions.

(iii) Simulated use testing must demonstrate that the device can be inserted, tracked, activated, and removed without device damage and that the device is able to function as intended (*e.g.,* remove IVC filter without damage) under challenging clinical use conditions.

(iv) Performance testing must demonstrate that the product is visible under fluoroscopic techniques.

(v) Performance testing must demonstrate that the device does not kink when subjected to clinically relevant tortuosity.

(3) Compatibility testing with laser generators must include:

(i) Electrical safety, electromagnetic compatibility testing, and electromagnetic interference testing must be conducted for all devices that contain electrical components.

(ii) Software verification, validation, and hazard analysis must be conducted for all devices that contain software.

(iii) Laser output characterization and performance testing, including verification of calibration reliability, energy output, and repetition rate, and laser lifetime testing, must be conducted.

(4) All patient-contacting components must be demonstrated to be biocompatible.

(5) Performance data must demonstrate the sterility and non-pyrogenicity of patient contacting components of the device that are provided sterile.

(6) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and system functionality over the established shelf life.

(7) In vivo safety testing must demonstrate that the device does not cause soft tissue damage or device damage under worst case clinical use conditions.

(8) Labeling must include the following:

(i) A detailed summary of the device technical parameters and materials of the device;

(ii) A summary of the clinical performance testing conducted with the device; and

(iii) A shelf life.

(9) A training program must be provided to ensure that users can safely and reliably use the device per its instructions for use.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–08426 Filed 4–29–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2026–N–4269]

Medical Devices; Neurological Devices; Classification of the Brain Temperature Measurement System

AGENCY: Food and Drug Administration, HHS.