''Sacramento Mather Airport, CA.'' The geographic coordinates of the airport are updated to match the FAA's database. Lastly, Sacramento Mather Airport has part-time Class D airspace but does not include a part-time statement within the legal description. Part-time verbiage is added to the legal description to properly describe the airspace.

Regulatory Notices and Analyses

The FAA has determined that this 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 Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 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 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

Paragraph 5000 Class D Airspace

* * * * *

AWP CA D Sacramento, CA [Amended]

Sacramento Mather Airport, CA
(Lat. 38°33′19″ N, long 121°17′50″ W)

That airspace extending upward from the surface to and including 2,600 feet MSL within a 4.5-mile radius of the airport, and within 1.9 miles each side of the 061° bearing from the airport, extending from the 4.5-mile radius to 6.3 miles northeast of the airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

* * * * *

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

* * * * *

AWP CA E5 Sacramento, CA [New]

Sacramento Mather Airport, CA
(Lat. 38°33′19″ N, long. 121°17′50″ W)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of the airport from the 075° bearing clockwise to the 210° bearing, and within 2.8 miles northwest and 2.4 miles southeast of the 054° bearing extending from the airport to 12.7 miles northeast, and within 6 miles northwest and 9 miles southeast of the 054° bearing extending from 12.7 miles northeast of the airport to 37 miles northeast, and within 2.8 miles either side of the 234° bearing extending from the airport to 10.9 miles southwest.

* * * * *

Issued in Des Moines, Washington, on September 3, 2024.

B.G. Chew,

Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2024–20198 Filed 9–6–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2024–N–4086]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Blood Collection Device for Cell-Free Nucleic Acids

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the blood collection device for cell-free nucleic acids 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 the blood collection device for cell-free nucleic acids' classification. We are taking this action because we have determined that classifying the device into class II (special controls) 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 September 9, 2024. The classification was applicable on August 7, 2020.

FOR FURTHER INFORMATION CONTACT: Lindsey Coe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3556, Silver Spring, MD 20993–0002, 240–402–5267, *Lindsey.Coe@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the blood collection device for cell-free nucleic acids as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness.

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 as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 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 (see 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 21 CFR 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 application 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 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.

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 510(k) process, when necessary, to market their device.

II. De Novo Classification

On January 10, 2020, FDA received Streck, Inc.'s request for De Novo classification of the Cell-Free DNA BCT. 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, 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 21 U.S.C. 360c(a)(1)(B)). 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 August 7, 2020, 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 862.1676.[1] We have named the generic type of device blood collection device for cell-free nucleic acids, and it is identified as intended for medical purposes to collect, store, transport, and handle blood specimens and to stabilize and isolate cell-free nucleic acid components prior to further testing.

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

TABLE 1—BLOOD COLLECTION DEVICE FOR CELL-FREE NUCLEIC ACIDS RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Blood pathogen exposure/Injury.	Certain design verification and validation.
Failure to collect and transport sample.	Certain design verification and validation.
Insufficient sample quantity and quality.	Certain design verification and validation.

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. 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 order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

[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.

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 individually or cumulatively 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 system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 862

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 862 is amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for part 862 continues to read as follows:

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

■ 2. Add § 862.1676 to subpart B to read as follows:

§ 862.1676 Blood collection device for cell-free nucleic acids.

(a) *Identification.* A blood collection device for cell-free nucleic acids is a device intended for medical purposes to collect, store, transport, and handle blood specimens and to stabilize and isolate cell-free nucleic acid components prior to further testing.

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

(1) Design verification and validation documentation must include appropriate design inputs and design outputs that are essential for the proper functioning of the device for its intended use, including all of its indications for use, and must include the following:

(i) Documentation demonstrating that appropriate, as determined by FDA, measures are in place (*e.g.,* validated device design features and specifications) to ensure that users of blood collection device for cell-free nucleic acids devices are not exposed to undue risk of bloodborne pathogen exposure and operator injury during use of the device, including blood collection, transportation, and centrifugation processes.

(ii) Documentation demonstrating that appropriate, as determined by FDA, measures are in place (*e.g.,* validated device design features and specifications) to ensure that the device reproducibly and reliably collects, transports, stabilizes, and isolates cell-free nucleic acids of sufficient yield and quality suitable for downstream applications as appropriate for its intended use. At a minimum, these measures must include:

(A) Data demonstrating that blood samples collected in the device have reproducible cell-free nucleic acid yields that are suitable, as determined by FDA, for downstream testing as appropriate for the intended use, including estimates of within-lot, within-device, and lot-to-lot variability;

(B) Data demonstrating that cell-free nucleic acid yields isolated from blood specimens collected into the device do not add clinically significant bias to test results obtained using the downstream application(s) described in the intended use. For devices indicated for use with multiple downstream applications, data demonstrating acceptable performance for each type of claimed use or, alternatively, an appropriate, as determined by FDA, clinical justification for why such data are not needed;

(C) Data demonstrating that the device appropriately stabilizes cell-free nucleic acids after sample collection, during storage, and during transport over the claimed shelf life of the device;

(D) Data demonstrating that samples collected in the device have minimal levels of contamination with other types of nucleic acids present in cells or cellular components, and that these levels of contamination do not interfere with downstream testing;

(E) Data from analytical or clinical studies that demonstrate that, when used as intended, the device consistently draws a blood sample volume that is within the indicated fill range;

(F) Data from analytical or clinical studies that demonstrate that, when used as intended, cell-free nucleic acid yield, stability, and quality are not significantly impacted by interference due to other parts of the device (such as reduced or excess active ingredient) or specimen collection and processing procedures (such as hemolysis, centrifugation, or mixing of blood with anticoagulant or additives); and

(G) Data from analytical studies that demonstrate that the device is suitable for its intended use across all storage and sample handling conditions described in the device labeling, including device shelf life and shipping conditions (*e.g.,* temperature, humidity, duration).

(iii) A protocol, reviewed and determined acceptable by FDA, that specifies the verification and validation activities that will be performed for anticipated device modifications to reevaluate performance claims or performance specifications. This protocol must include a process for assessing whether a modification to technology, engineering, performance, materials, specifications, or indications for use, or any combination thereof, could significantly affect the safety or effectiveness of the device. The protocol must include assessment metrics, acceptance criteria, and analytical methods for the performance testing of changes.

Dated: September 4, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20254 Filed 9–6–24; 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–2024–N–4059]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Endoscopic Pancreatic Debridement Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the endoscopic pancreatic debridement device 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 the endoscopic pancreatic debridement device's classification. We are taking this action because we have determined that classifying the device into class II (special controls) 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.

DATES: This order is effective September 9, 2024. The classification was applicable on December 23, 2020.

FOR FURTHER INFORMATION CONTACT: Thelma Valdes, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2610, Silver Spring, MD 20993–0002, 301–796–9621, *Thelma.Valdes@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the endoscopic pancreatic debridement device as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness.

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 as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 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