(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on December 19, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–28270 Filed 12–28–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0906; Airspace Docket No. 21–ASO–27]

RIN 2120–AA66

Amendment and Establishment of Area Navigation (RNAV) Routes; Eastern United States

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 December 12, 2022 that amends three area navigation (RNAV) routes (T-routes), and establishes five T-routes. In the final rule, the HITMN, TN, waypoint (WP), the TMPSN, TN, WP, and the TROPP, SC, WP were misspelled, and the PENCE, TN, point was misidentified as a WP instead of a Fix. The action makes editorial corrections to the above points to match the FAA National Airspace System Resource (NASR) database information.

DATES: Effective date 0901 UTC, February 23, 2023. 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.

ADDRESSES: FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule in the *Federal* Register (87 FR 75925; December 12, 2022) amending three RNAV T-routes and establishing five T-routes. Subsequent to publication, the FAA determined that the HITMN, TN, WP was misspelled in the discussion of route T–439. In addition, the TMPSN, TN, WP was misspelled, and the PENCE, TN point was misidentified as a WP instead of a Fix in the regulatory text description of T–424. Also, the TROPP, SC, WP was misspelled in the regulatory text description of T–441. Similarly, the PENCE, TN point in the regulatory text of route T–441 was misidentified as a WP instead of a Fix. This rule corrects the above errors.

These are editorial changes only to match the information in the FAA NASR database and do not alter the alignment of the affected T-routes.

United States RNAV T-routes are published in paragraph 6011 of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The RNAV routes listed in this document will be subsequently published in FAA Order JO 7400.11.

Correction to Final Rule

The references to RNAV routes T–439, T–424, and T–441 published in the **Federal Register** of December 12, 2022 (87 FR 75925), FR Doc. 2022–26735, are corrected as follows:

■ 1. On page 75926, in column 2, under the heading ''The Rule'' in the text for ''T–439,'' revise ''T–439 is a new route that extends from the PIGON, AL, Fix, to the HITMAN, TN, WP.'' to read ''T–439 is a new route that extends from the PIGON, AL, Fix, to the HITMN, TN, WP.'' to match FAA NASR database information.

■ 2. On page 75927, correct the table for T–424 SMRRF, TN to DBRAH, VA [New] to read:

T–424 SMRRF, TN to DBRAH, VA [New]

SMRRF, TN	WP	(Lat. 35°33′43.23″ N, long. 086°26′20.24″ W)
TMPSN, TN	WP	(Lat. 35°46′51.54″ N, long. 084°58′43.15″ W)
EDDDY, TN	WP	(Lat. 35°54′17.33″ N, long. 083°53′41.72″ W)
CRECY, TN	WP	(Lat. 35°58′52.61″ N, long. 083°38′24.36″ W)
PENCE, TN	FIX	(Lat. 36°01′09.80″ N, long. 083°31′26.31″ W)
HORAL, TN	WP	(Lat. 36°26′13.99″ N, long. 082°07′46.48″ W)
DANCO, VA	WP	(Lat. 37°05′15.75″ N, long. 080°42′46.45″ W)
DBRAH, VA	WP	(Lat. 37°20′34.14″ N, long. 080°04′10.75″ W)

■ 3. On page 75928 correct the table for T–441 TROPP, SC to PENCE, TN [New] to read:

T–441 TROPP, SC to PENCE, TN [New]

TROPP, SC	WP	(Lat. 32°53′40.00″ N., long. 080°02′16.59″ W)
CAYCE, SC	WP	(Lat. 33°51′26.13″ N., long. 081°03′14.76″ W)
BURGG, SC	WP	(Lat. 35°02′00.55″ N., long. 081°55′36.86″ W)
STYLZ, NC	WP	(Lat. 35°24′22.83″ N., long. 082°16′07.01″ W)
MUMMI, NC	FIX	(Lat. 35°39′48.60″ N., long. 082°47′30.15″ W)
PUPDG, NC	WP	(Lat. 35°46′30.08″ N., long. 083°03′40.16″ W)
PENCE, TN	FIX	(Lat. 36°01′09.80″ N., long. 083°31′26.31″ W)

* * * * *

Issued in Washington, DC, on December 23, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–28361 Filed 12–28–22; 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–2022–N–3186]

Medical Devices; Cardiovascular Devices; Classification of the Extracorporeal System for Carbon Dioxide Removal

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the extracorporeal system for carbon dioxide removal 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 extracorporeal system for carbon dioxide removal'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 December 29, 2022. The classification was applicable on November 13, 2021.

FOR FURTHER INFORMATION CONTACT: Alejandra Cambonchi, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2253, Silver Spring, MD 20993–0002, 301–796–0552, *Alejandra.Cambonchi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the extracorporeal system for carbon dioxide removal as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part 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 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. 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 less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On August 30, 2021, FDA received ALung Technologies, Inc.'s request for De Novo classification of the Hemolung Respiratory Assist System. 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 November 13, 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 870.4150.[1] We have named the generic type of device extracorporeal system for carbon dioxide removal, and

[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.