

AIRAC date	State	City	Airport name	FDC No.	FDC date	Procedure name
30–Nov–23 .....	CT	Bridgeport .....	Bridgeport/Sikorsky .....	3/3119	10/11/23	ILS OR LOC RWY 6, Amdt 10B.
30–Nov–23 .....	CT	Bridgeport .....	Bridgeport/Sikorsky .....	3/3122	10/11/23	RNAV (GPS) RWY 29, Amdt 2B.
30–Nov–23 .....	CT	Bridgeport .....	Bridgeport/Sikorsky .....	3/3123	10/11/23	RNAV (GPS) RWY 24, Amdt 1B.
30–Nov–23 .....	CT	Bridgeport .....	Bridgeport/Sikorsky .....	3/3125	10/11/23	RNAV (GPS) RWY 6, Amdt 1B.
30–Nov–23 .....	MI	Hancock .....	Houghton County Meml ...	3/6218	10/16/23	RNAV (GPS) RWY 25, Amdt 1B.
30–Nov–23 .....	KS	Manhattan .....	Manhattan Rgnl .....	3/6770	10/19/23	ILS OR LOC RWY 3, Amdt 8.
30–Nov–23 .....	MA	Plymouth .....	Plymouth Muni .....	3/8906	10/20/23	RNAV (GPS) RWY 33, Amdt 1.
30–Nov–23 .....	MA	Plymouth .....	Plymouth Muni .....	3/8908	10/20/23	RNAV (GPS) RWY 15, Orig–A.

[FR Doc. 2023–24660 Filed 11–8–23; 8:45 am]  
 BILLING CODE 4910–13–P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 864**

[Docket No. FDA–2023–N–4487]

**Medical Devices; Hematology and Pathology Devices; Classification of the Container System for the Processing and Storage of Red Blood Cell Components Under Reduced Oxygen Conditions**

**AGENCY:** Food and Drug Administration, Department of Health and Human Services (HHS).

**ACTION:** Final amendment; final order.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is classifying the container system for the processing and storage of Red Blood Cell components under reduced oxygen conditions 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 classification of the container system for the processing and storage of Red Blood Cell components under reduced oxygen conditions. 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 November 9, 2023. The classification was applicable on September 15, 2023.

**FOR FURTHER INFORMATION CONTACT:** Karen Fikes, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Upon request, FDA has classified the container system for the processing and storage of Red Blood Cell components under reduced oxygen conditions 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). 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 5, 2022, FDA received Hemanext, Inc.’s request for De Novo classification of the Hemanext One. 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 September 15, 2023, 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 864.9115.<sup>1</sup> We have named the generic type of device container system for the processing and storage of Red Blood Cell components under reduced

oxygen conditions, identified as a device intended for medical purposes that is used to process and store Red Blood Cell components and reduce oxygen levels in the storage environment.  
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—CONTAINER SYSTEM FOR THE PROCESSING AND STORAGE OF RED BLOOD CELL COMPONENTS UNDER REDUCED OXYGEN CONDITIONS RISKS TO HEALTH AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Toxicity that can result from contact of the component materials of the device with the red blood cells or patient's body.	Biocompatibility evaluation.
Toxicity of leached materials, or residual chemical sterilant, when in contact with red blood cells or transfused to patient.	Extractables and leachables testing.
Infection .....	Sterilization validation; Endotoxin testing; and Container closure evaluation.
Transfusion of poor quality red blood cells because of inadequate storage conditions or device malfunction.	Nonclinical and clinical studies; Shelf-life testing; and Performance testing.
Blood exposure because of device malfunction .....	Performance testing.
Transfusion of poor quality red blood cells due to processing of Red Blood Cells components collected from donors with hemoglobin S.	Labeling.

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. At the time of classification, container system for the processing and storage of Red Blood Cell components under reduced oxygen conditions is 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.

**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 21 CFR 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 part 801, regarding labeling, have been approved under OMB control number 0910–0485.

**List of Subjects in 21 CFR Part 864**

Blood, Medical devices, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 864 is amended as follows:

**PART 864—HEMATOLOGY AND PATHOLOGY DEVICES**

- 1. The authority citation for part 864 continues to read as follows:

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

- 2. Add § 864.9115 to subpart J to read as follows:

**§ 864.9115 Container system for the processing and storage of Red Blood Cell components under reduced oxygen conditions.**

(a) *Identification.* A container system for the processing and storage of Red Blood Cell components under reduced oxygen conditions is a device intended for medical purposes that is used to process and store Red Blood Cell components and reduce oxygen levels in the storage environment.

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

<sup>1</sup> 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.

(1) The intended use of the device must specify:

(i) The Red Blood Cell components that can be processed and stored including acceptable anticoagulants and additive solutions;

(ii) The hold time after Red Blood Cell component collection;

(iii) The processing capacity (volume) of the device; and

(iv) The storage temperature and dating period of processed Red Blood Cell components.

(2) Studies must demonstrate that the device is biocompatible and include detailed documentation of the biocompatibility evaluation.

(3) Performance testing and nonclinical studies must include a detailed study of leached materials extracted under conditions similar to clinical usage of the device, and a toxicologic risk assessment of those extracted or leached materials.

(4) Performance testing must support sterility of the device and include sterilization validation, endotoxin testing, and container closure integrity evaluation.

(5) Nonclinical and clinical studies must include evaluation of red blood cell quality throughout the duration of storage based on in vitro and in vivo studies, including hemolysis and red blood cell survival and recovery.

(6) Performance studies must include:

(i) Detailed documentation of functional and mechanical testing, including evaluation of oxygen and, if applicable, carbon dioxide levels during Red Blood Cell components storage; and

(ii) Detailed documentation of device shelf-life testing demonstrating continued sterility, package integrity, and functionality over the identified shelf life.

(7) The labeling must include a contraindication against processing Red Blood Cell components collected from donors with hemoglobin S.

Dated: November 3, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 100

[Docket No. USCG-2023-0783]

#### Special Local Regulations; OPA World Championships; Gulf of Mexico; Englewood, FL

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notification of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce special local regulations for the OPA World Championships to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Seventh Coast Guard District identifies the regulated area for this event in Englewood Beach, FL. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any designated representative.

**DATES:** The regulations in 33 CFR 100.703 will be enforced daily from 8 a.m. until 6 p.m. on November 18, 2023, through November 19, 2023, for the location identified in Item 8 in table 1 to § 100.703.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notification of enforcement, call or email Marine Science Technician First Class Mara Brown, Sector St. Petersburg Prevention Department, Coast Guard; telephone 813-228-2191, email [mara.j.brown@uscg.mil](mailto:mara.j.brown@uscg.mil).

**SUPPLEMENTARY INFORMATION:** *The Coast Guard will enforce the special local regulations in 33 CFR 100.703 for the OPA World Championships identified in Table 1 to § 100.703, Item No. 8, from 8 a.m. until 6 p.m., on November 18, 2023, through November 19, 2023. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for recurring marine events, Sector St. Petersburg, § 100.703, Table 1 to § 100.703, Item No. 8, specifies the locations of the regulated area for the OPA World Championships which encompasses portions of the Gulf of Mexico near Englewood, FL. During the enforcement periods, as reflected in § 100.703(c), if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander or any designated representative.*

In addition to this notice of enforcement in the **Federal Register**, the

Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners, marine information broadcasts, or both.

Dated: November 2, 2023.

**Michael P. Kahle,**

*Captain, U.S. Coast Guard, Captain of the Port St. Petersburg.*

[FR Doc. 2023-24787 Filed 11-8-23; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket No. USCG-2023-0883]

#### Safety Zone; Military Ocean Terminal Concord Safety Zone, Suisun Bay, Military Ocean Terminal Concord, CA

**AGENCY:** Coast Guard, Department of Homeland Security (DHS).

**ACTION:** Notification of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce a safety zone in the navigable waters of Suisun Bay, off Concord, CA, in support of explosive on-loading to Military Ocean Terminal Concord (MOTCO) on November 13, 2023, through November 20, 2023. This safety zone is necessary to protect personnel, vessels, and the marine environment from potential explosion within the explosive arc. The safety zone is open to all persons and vessels for transitory use, but vessel operators desiring to anchor or otherwise loiter within the safety zone must obtain the permission of the Captain of the Port San Francisco or a designated representative. All persons and vessels operating within the safety zone must comply with all directions given to them by the Captain of the Port San Francisco or a designated representative.

**DATES:** The regulations in 33 CFR 165.1198 will be enforced from 12:01 a.m. on November 13, 2023, until 11:59 p.m. on November 20, 2023.

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this notification of enforcement, call, or email LT Abby Hamann, U.S. Coast Guard Sector San Francisco, Waterways Management Division, at 415-399-3585, [SFWaterways@uscg.mil](mailto:SFWaterways@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce the safety zone in 33 CFR 165.1198 for the Military Ocean Terminal Concord, CA (MOTCO) regulated area from 12:01 a.m. on November 13, 2023, until 11:59 p.m. on