GRANT – DE NOVO
September 15, 2023

Hemanext, Inc.
Attention: Laura Daniels
99 Hayden Avenue, Suite 620
Lexington, MA 02421

Re: BR220665

Trade/Device Name:	Hemanext One
Regulation Number:	21 CFR 864.9115
Regulation Name:	Container system for the processing and storage of Red Blood Cell components under reduced oxygen conditions
Regulatory Class:	Class II
Product Code:	QYC
Dated:	December 30, 2021
Received:	January 5, 2022

Dear Laura Daniels:

The Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Hemanext One, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> Blood container set used to process and store Red Blood Cells Leukocytes Reduced, O2 /CO2 Reduced.
>
> HEMANEXT ONE is intended to process and store CP2D/AS-3 Red Blood Cells, Leukocytes Reduced (LR RBC) that have been prepared within the standard 8-hour hold time. Processing of Red Blood Cells with the HEMANEXT ONE system must be initiated within 8 hours of collection and completed within 12 hours of collection. The Red Blood Cells must be processed at room temperature (20-26 °C). The HEMANEXT ONE system limits O2 and CO2 levels in the storage environment. Red Blood Cells Leukocytes Reduced, O2 /CO2 Reduced may be stored for up to 42 days at 1-6 °C. HEMANEXT ONE is used for volumes no greater than 350 mL of LR RBC.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Hemanext One, and substantially equivalent devices of this generic type, into Class II under the generic name Container system for the processing and storage of Red Blood Cells under reduced oxygen conditions.

FDA identifies this generic type of device as:

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

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On January 5, 2022, FDA received your De Novo requesting classification of the Hemanext One. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Hemanext One into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the Hemanext One can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

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 Container closure evaluation
Transfusion of poor-quality red blood cells because of inadequate storage conditions or device malfunction	Non-clinical and clinical studies Shelf-life testing 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

In combination with the general controls of the FD&C Act, the Container system for the processing and storage of Red Blood Cell components under reduced oxygen conditions is subject to the following special controls:

(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.

(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 non-clinical 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.

(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:

(i) A contraindication against processing Red Blood Cell components collected from donors with hemoglobin S.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CBERProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Container system for the processing and storage of Red Blood Cell components under reduced oxygen conditions they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch

(HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Courtney White at (301) 796-0636 or by email at courtney.white@fda.hhs.gov.

Sincerely,

Orieji Illoh, MD
Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics Evaluation and Research