May 31, 2024

eDonorSoft, LLC
Attention: Rasiah Jegatheswaran
1619 Whitfield Street
Sugarland, TX 77479

Re: BK230958

Trade/Device Name:	HemDonER 1.0.1
Regulation Number:	21 CFR 864.9165
Regulation Name:	Blood Establishment Computer Software and Accessories
Regulatory Class:	Class II
Product Code:	MMH
Dated:	October 2, 2023
Received:	October 2, 2023

Dear Rasiah Jegatheswaran:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the **Federal Register**.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

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

Enclosure: Indications for Use

Indications for Use

510(k) Number: BK230958

Device Name: HemDonER 1.0.1

Indications for Use:

HemDonER version 1.0.1 is a web application designed to manage plasma donation center activities. This application aims to improve the accuracy, efficiency, and safety of plasma donations by creating an organized secure system for managing the whole plasma donation process from registration of donors to collection of plasma and to the final distribution of the product.

The HemDonER version 1.0.1 provides management controls and information service modules designed to assist the staff in the core functions by addressing various aspects of donor management and operational oversight.

The HemDonER version 1.0.1 medical device includes the following modules:

1. Donor Registration: Capture and store donors' personal details, contact information, and medical history and educate donors about the impact of plasma donations and the information related to prior and post-donation care.

2. Donor Health Screening and Assessment: Determine donor eligibility by administration, recording, and tracking various screening tests, medical questionnaire information received from a Computer Assisted Self-Interview (CASI) system, consent agreements, and medical evaluations.

3. Donation Tracking: Monitor donation frequency. Record and track each donation and capture the information on collection time, date, volume, and any incidents that occurred during the collection process.

4. Samples management: Manages the tasks required to collect and ship samples, receive test results, and determine donor and unit status and suitability based on the test results received from the lab.

5. Unit inventory and Shipment Management: Track the inventory of collected plasma and manage the tasks required to handle units from collection until they are released for shipment based on the test results received and donor eligibility information entered and stored in the application. Capture, track, and report unsuitable units at the center and provide Lookback Reports based on Post donation information.

6. Regulatory Support: Record and track equipment calibration, validation, and maintenance. Record and track employee training. Maintain documentation and records necessary for audits and compliance checks.

HemDonER version 1.0.1 provides secure access controls to protect donor information, maintains confidentiality, and ensures data protection and privacy regulations.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CBER, Office of Blood Research and Review (OBRR)

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Division Sign-Off, Office of Blood Research and Review