EDONORSOFT

**510(k) Summary**

In accordance with 21 CFR 807.87(h), a 510(k) summary is included that meets the conditions as outlined for a 510(k) summary in 21 CFR 807.92.

**Submitter Information:**

Company Name: EDONORSOFT LLC.

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**Official Correspondence regarding this 510(k):**

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**Device:**

**Device Classification Name:** Software, Blood Bank, Web Products

**Trade Name:** HemDonER 1.0.1

**Common Name:** Blood Establishment Computer Software

**Review Panel:** Hematology

**Classification Product Code:** MMH

**Device Classification Regulation:** 21 CFR 864.9165

**Device Class:** Class II

**Predicate Device:**

| Predicate | Trad Name | Manufacturer | 510(k) Number | Classification product code |
|---|---|---|---|---|
| Predicate 1 | ePROGESA–Version 5.0.1 | MAK-SystemSAS International Group | BK080002 | MMH |

**Device Description**:

The HemDonER is a web application manufactured by EDONORSOFT LLC designed for plasma donor centers and organizations collecting plasma.

It is designed to aid/assist qualified and trained personnel to support the major operations within their facilities, helping ensure plasma unit safety and traceability.

The main modules available in HemDonER include:

- Donation Collection Management
- Donor Management
- Donor, Donation, and Plasma Laboratory Testing
- Plasma Preparation Management
- Product Inventory Management
- Quality Control Management
- Distribution Management
- Traceability
- Equipment Management
- Lookback and Surveillance Management

- Sample Storage
- Standard Operating Procedure Management
- Interfaces
- Report Management
- Security

**Intended 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.

**Nonclinical Trials**

Numerous unit testing, code reviews, and system-level testing were performed by EDONORSOFT LLC.

The submitted device has undergone comprehensive verification and validation testing. System testing is performed as part of the validation activities to ensure that HemDonER software meets its intended use, including critical safety requirements. This process is based on scripts prepared and traced to the functional requirements and the hazard analysis.

This activity takes place at EDONORSOFT following the software installation and qualification procedure. The test cases also encompass electronic data capture functionalities (interfaces) based on data samples built to meet the corresponding requirements.

**Clinical Trials**

Clinical performance testing is not applicable for the HemDonER as it is a software-only product.

**Summary of Safety and Effectiveness**

The HemDonER device was developed in accordance with relevant regulations. The software was thoroughly tested, including system verification and validation, to ensure it was adequately developed and functioned according to its intended use.

Based on the testing results and the functional and technological comparison, the HemDonER device is safe for its intended use and substantially equivalent to the predicate device in terms of intended use, functionality, technological characteristics, safety, and effectiveness.