# *510(k) Summary*
## *(in accordance with 21 CFR §807.92)*

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| ***Submission Date:*** | 02 May 2023 |
| ***Submitter:*** | GPI USA, Inc.<br>4900 Woodway Drive, Suite 680<br>Houston, TX 77056<br>United States of America |
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| ***Manufacturing Site:*** | GPI USA, Inc.<br>4900 Woodway Drive, Suite 680<br>Houston, TX 77056<br>United States of America |
| ***Trade Name:*** | e-Delphyn Donor v11.2 (US) |
| ***Common Name:*** | Blood establishment computer software and accessories |
| ***Classification Name:*** | Blood establishment computer software and accessories |
| ***Classification Regulation:*** | 21 CFR §864.9165 |
| ***Product Code:*** | MMH |

***Substantially Equivalent Devices:***

| *New GPI USA Model* | *Predicate 510(k) Number* | *Predicate Manufacturer / Model* |
|---|---|---|
| e-Delphyn Donor v11.2 (US) | BK200515 | Hemasoft Software S.L. / e-Delphyn Donor v11.0.0.1<br><br>(e-Delphyn Donor now owned by GPI USA, Inc.) |

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***Device Description:*** GPI USA, Inc. e-Delphyn Donor v11.2 (US) (e-Delphyn Donor) is a web-enabled, modular, computerized software as a medical device (SaMD) system that is intended to be used by trained personnel to aid in the management and documentation of donation, processing, storage and distribution processes of all blood components.

The system is built using Java technology and other Java, web-related architecture which enables the system to work from small-scale hospital operations to multiple-site health care providers and supports compliance with the global standard for the terminology, identification, coding and labeling of medical products of human origin (including blood, cell, tissue, milk, and organ products): *International Council for Commonality in Blood Banking Automation (ICCBBA) United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components using ISBT 128 (2013).*

There are three (3) modules in e-Delphyn Donor:

*Blood Bank Module*

The Blood Bank Module provides functionality for:

- registering donors and bags,
- deferring, merging and qualifying donors,
- registering the outcome of the Donor History Questionnaire,
- recording medical screening data,
- phenotype RBC/HLA searching and matching, and
- phlebotomy information and record review.

The Blood Bank Module also provides functionality for:

- entering and evaluating test results in accordance with the decision rules,
- processing units into components,
- managing inventory and distribution of units, and
- managing therapeutic and autologous/directed donations requests.

*User Module*

The User Module provides functionality for:

- configuring facilities, user profiles and individual users, and
- for viewing activities for a particular user.

*Configuration Module*

The Configuration Module provides functionality to:

- allow certain users access to adapt the system to the local terms and processes; and
- to define some lookup or drop-down fields.

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***Intended Use:*** e-Delphyn Donor is a web enabled modular computerized system intended to be used by trained personnel to aid in donor management. The functionalities include:

- Registering, deferring, merging and qualifying donors.
- Registering bags.
- Recording the outcomes of the Donor History Questionnaire (DHQ).
- Recording medical screening data and phlebotomy information.
- Entering and evaluating test results in accordance with the decision rules.
- Processing units in components.
- Phenotype RBC/HLA searching and matching.
- Managing storage, inventory and distribution of units.
- Managing therapeutic and autologous/directed donations requests.

***Technology Comparison:*** e-Delphyn Donor v11.2 (US) employs the same technological characteristics as the predicate device.

| ***Characteristic*** | ***Hemasoft Software, S.L.<br>e-Delphyn Donor v11.0.0.1<br>(BK200515)*** | ***GPI USA<br>e-Delphyn Donor v11.2 (US)<br>(BK220791)*** |
|---|---|---|
| *Indications for Use* | e-Delphyn Donor is a web enabled modular computerized system intended to be used by trained personnel to aid in donor management. The functionalities include:<br>• Registering, deferring, merging and qualifying donors.<br>• Registering bags.<br>• Recording the outcomes of the Donor History Questionnaire (DHQ).<br>• Recording medical screening data and phlebotomy information.<br>• Entering and evaluating test results in accordance with the decision rules.<br>• Processing units in components.<br>• Managing storage, inventory and distribution of units.<br>• Managing therapeutic and autologous/directed donations requests. | e-Delphyn Donor is a web enabled modular computerized system intended to be used by trained personnel to aid in donor management. The functionalities include:<br>• Registering, deferring, merging and qualifying donors.<br>• Registering bags.<br>• Recording the outcomes of the Donor History Questionnaire (DHQ).<br>• Recording medical screening data and phlebotomy information.<br>• Entering and evaluating test results in accordance with the decision rules.<br>• Phenotype RBC/HLA searching and matching.<br>• Managing storage, inventory and distribution of units.<br>• Managing therapeutic and autologous/directed donations requests. |

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***Technology Comparison (continued):***

| *Characteristic* | *Hemasoft Software, S.L. e-Delphyn Donor v11.0.0.1 (BK200515)* | *GPI USA e-Delphyn Donor v11.2 (US) (BK220791)* |
|---|---|---|
| *Components* | Preparation, manufacturing, testing, labeling. | Same, but testing now includes human leukocyte antigen (HLA) typing. |
| *Donor Product Management* | Inventory control including<br>• Storage.<br>• Distribution.<br>• Quarantine.<br>• Lookback.<br>• Phenotype RBC searching. | Inventory control including<br>• Storage.<br>• Distribution.<br>• Quarantine.<br>• Lookback.<br>• Phenotype RBC/HLA searching and matching. |

***Predicate Device Comparison:*** e-Delphyn Donor v11.2 (US) employs the same intended use, indications for use and technological characteristics as the predicate device.

***Summary of Performance Testing:***

*Software*

e-Delphyn Donor v11.2 (US) software was designed and developed according to a robust software development process and was rigorously verified and validated.

Software information is provided in accordance with internal requirements and the following guidance documents and standards:

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05.*
- *FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99.*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.*
- *FDA guidance: Content of premarket submissions for management of cybersecurity in medical devices, 02 Oct 14.*
- *FDA guidance: Cybersecurity for networked medical devices containing off-the-shelf (OTS) software, 14 Jan 05.*
- *ISO 14971: 2019, Medical devices – Application of risk management to medical devices.*

Test results indicate that e-Delphyn Donor v11.2 (US) complies with its predetermined specifications and the guidance documents.

*Performance Testing – Bench*

e-Delphyn Donor v11.2 (US) was tested for performance in accordance with internal requirements including:

- *Risk Control Measure Verification.*
- *Functional Verification and Validation*

Verification results indicated that e-Delphyn Donor v11.2 (US) complies with internal requirements.

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***Conclusion***

Verification and validation activities were conducted to establish the performance and safety characteristics of the device modifications made to e-Delphyn Donor v11.2 (US) Donor. The results of these activities demonstrate that e-Delphyn Donor v11.2 (US) is as safe and as effective in comparison to the predicate device when used in accordance with its intended use and labeling. Therefore, e-Delphyn Donor v11.2 (US) is considered substantially equivalent to the predicate device.