

510(k) Summary for e-Delphyn Donor

Submitter's Name Hemasoft Software, S.L.
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Establishment Registration Number Will register within 30 days after placing this device into commercial distribution

Date of Summary July 31, 2020

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Name of the Device e-Delphyn Donor

Common or Usual Name Blood Establishment Computer Software

Classification Name Blood establishment computer software and accessories.

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:

- 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
- Managing storage, inventory and distribution of units
- Managing therapeutic and autologous/directed donations requests.

Identification of the Legally Marketed Device (Predicate Device) MAK-SYSTEM SAS International Group ePROGESA -Version 5.0.1
510(k) BK080002 cleared May 13, 2008
Blood Establishment Computer Software (BECS)
Device Class: Class 2
Product Code: MMH

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Device Description

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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 the use of Information Standard for Blood and Transplant (ISBT) 128.

e-Delphyn Donor has been in use for more than 15 years, there are no known open anomalies and there have been 600 installations of Hemosoft e-Delphyn Donor software at sites outside of the US.

The following provides a high level overview of the three (3) e-Delphyn Donor modules:

Blood Bank Module

The Blood Bank Module provides functionality for registering, deferring, merging and qualifying donors; recording the outcome of the questionnaire; recording medical screening data and phlebotomy information. 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 as well as therapeutic and autologous/directed donations requests..

Users Module

The Users Module provides functionality for configuring access, 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 Comparison

Subject Device: e-Delphyn Donor

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- Recording the outcomes of the Donor History Questionnaire (DHQ)
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Predicate Device: ePROGESA 5.0.1, BK080002

ePROGESA is a modular, stand-alone blood bank and blood transfusion service software application that is specially designed to meet the needs of collecting blood, plasma, platelet\$, cord blood and/or transfusion services organizations to aid/assist qualified and trained personnel to support the major operations within their facilities.

ePROGESA is designed to undertake typical blood bank operations on fixed and mobile sites including but not limited to session planning and recruitment of donors, donor eligibility status including deferrals management, interactive health questionnaire, donation collection, component preparation and transformation, donor and donation laboratory testing, blood unit release, inventory and distribution of blood products and manufactured products, product quality control, blood products lookback and donor surveillance, HLA/RBC searching and matching.

ePROGESA also intends to support typical blood transfusion operations of order management, patient management, inventory and inventory selection, testing, further manufacturing, release and distribution of blood products and manufactured products, track product disposition and transfusion history.

ePROGESA also includes interfaces for National Deferred Donor Register (NDDR), LIMS and Laboratory Instruments which assist trained laboratory personnel in the transfer and integration of test results to the ePROGESA software.

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Device Comparison Table

	Subject Device e-Delphyn Donor Version 11.0.0.1	Predicate ePROGESA 5.0.1 BK080002
Application Language	Java	Java
Database	Microsoft SQL Server 2014 SP2-GDR	Oracle Relational Database Management System
Architecture	N-tier application architecture composed of presentation tier, a domain logic tier, and a data storage tier	Highly scalable, multi-tier client server or Thin Client
Server Software	<ul style="list-style-type: none"> • Windows Server 2016 • Java SDK Kit 1.8.0_201 • Apache Tomcat (8.5.42) 	<ul style="list-style-type: none"> • SUN Solaris 10.5 or IBM AIX 5 or HP/UX 11 or Linux • WebSphere • WebLogic • Tomcat
Server Hardware Platform	<ul style="list-style-type: none"> • Intel Xeon E5-2680 v4 @ 2.40 GHz • 32GB RAM 	<ul style="list-style-type: none"> • SUN VSeries or IBM PSeries or HP9000 or Intel-Xeon server
Workstation Software	<ul style="list-style-type: none"> • Internet Explorer 11 • Adobe Acrobat Reader DC 2020.009 • Windows 8.1 or Windows 10 	Microsoft Windows 2000 or Windows XP or Vista
Workstation Hardware Platform	<ul style="list-style-type: none"> • 2 GHz processor (Intel Core i5 processor) • 4 GB of RAM • 128 GB hard disk 	<ul style="list-style-type: none"> • Pentium III or IV • Ethernet compatible or wireless network • Touch Screen: ELO ET 1715L • PDA: Symbol/Motorola MC3090 • Signature Table: TOPAZ Systems model T-L462-HSB • Fingerprint: Yubee DPL 1037000YB • Barcode scanner: Metrologic MS 9520
Platforms	Open industry standard	Open industry standard
Technology	J2EE web based	J2EE web based
Interfaces	<ul style="list-style-type: none"> • Donor-ID • e-Delphyn LIS Donor 	<ul style="list-style-type: none"> • National Deferred Donor Register • LIMS • Laboratory Instrument
Donor	No	Yes

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	Subject Device e-Delphyn Donor Version 11.0.0.1	Predicate ePROGESA 5.0.1 BK080002
recruitment		
Donor Identification	Donor demographics	Digitized tablet to capture donor signatures and donor photographs
Pre donation activities	Donor registration Donor eligibility Recording vitals Donor deferral	Donor administration
Donation Activities	Management of collection of blood components and apheresis products for autologous, allogeneic and therapeutic donations.	Collection administration including donor eligibility status (Blood, Plasma, Platelets, Cord Blood)
Components	Preparation, manufacturing, testing, labeling	Preparation and transformation with process documentation
Donor Product Management	Inventory control including storage, distribution, quarantine, lookback, Phenotype/RBC searching	Inventory management and distribution of blood products and manufactured products, product quarantine management, lookback and donor surveillance, HLA/RBC searching and matching.
Barcodes Supported	ISBT 128	ISBT 128
Product	Inventory management, delivery/shipping, product returns	Inventory management, delivery/shipping, product returns
Use of Wireless Technology	No	No

Description and Conclusion of Testing

Nonclinical Testing:

Code reviews, unit testing, and system level testing (including testing the mitigations for the identified hazards) was performed by Hemasoft Software, S.L.

External Validation Testing (Beta) was performed at one (1) beta site that included a total of 1642 test cases.

Clinical Testing:

Clinical testing was not required to demonstrate substantial equivalence of the e-Delphyn LIS Donor software” and was not performed.

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Conclusion:

There are no open anomalies known for e-Delphyn Donor version 11.0.0.1 for which this 510(k) is submitted.

Verification and validation activities were conducted to establish the performance and safety characteristics of the e-Delphyn Donor software. The results of these activities demonstrate that the e-Delphyn Donor software is as safe, as effective, and performs as well as or better than the predicate device when used in accordance with its intended use and labeling.

Therefore, the e-Delphyn Donor software is considered substantially equivalent to the predicate device.