

## 510(k) Summary for e-Delphyn Blood Management Software

<b>Submitter's Name</b>	Hemasoft Software, S.L.
<b>Address</b>	Antonio Lopez 249, 4° 3A, 28041 Madrid, Spain
<b>Establishment Registration Number</b>	Will register within 30 days after placing this device into commercial distribution
<b>Date of Summary</b>	July 24, 2015
<b>Telephone Number</b>	+34 91 500 10 87
<b>Fax Number</b>	+34 91 500 11 43
<b>Contact Person</b>	Virginia Burgos
<b>Name of the Device</b>	e-Delphyn Blood Management Software
<b>Common or Usual Name</b>	Blood Establishment Computer Software
<b>Classification Name</b>	Unclassified
<b>Indications for Use</b>	e-Delphyn is a web enabled modular computerized system that is intended to be used by trained personnel to aid in the management and documentation of donation, processing, storage and distribution processes for all blood components.
<b>Identification of the Legally Marketed Device (Predicate Device)</b>	MAK-SYSTEM SAS International Group ePROGESA -Version 5.0.1 510(k) BK080002 cleared May 13, 2008 Blood Establishment Computer Software (BECS) Device Class: Unclassified Product Code: MMH

## 510(k) Summary for e-Delphyn Blood Management Software

### Device Description

e-Delphyn is a web enabled modular computerized system that is intended to be used by trained personnel to aid in the management and documentation of donation, processing, storage and distribution processes for 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 the use of Information Standard for Blood and Transplant (ISBT) 128.

e-Delphyn has been in use for more than 10 years, there are no known open anomalies and there have been 492 installations of Hemasoft e-Delphyn software at sites outside of the US.

The following provides a high level overview of the three (3) eDelphyn Module:

### Blood Bank Module

The Blood Bank Module provides functionality for registering, deferring, merging and qualifying donors; recording the outcome of the Donor History Questionnaire (DHQ); 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.

### 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.

---

## 510(k) Summary for e-Delphyn Blood Management Software

### Intended Use Comparison

#### Subject Device:

##### **e-Delphyn Blood Management Software**

e-Delphyn is a web enabled modular computerized system that is intended to be used by trained personnel to aid in the management and documentation of donation, processing, storage and distribution processes for all blood components.

#### 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.

## 510(k) Summary for e-Delphyn Blood Management Software

**Device Comparison Table**

	<b>Subject Device</b> e-Delphyn Blood Management Software Version 7.1.0.0	<b>Predicate</b> ePROGESA 5.0.1 BK080002
<b>Application Language</b>	Java	Java
<b>Database</b>	Sql Server 2005 Express or Sql Server 2008 R2	Oracle Relational Database Management System
<b>Architecture</b>	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
<b>Server Software</b>	<ul style="list-style-type: none"> <li>• Windows Server 2008 R2 Enterprise</li> <li>• Windows Server 2003 R2</li> <li>• Java SDK Kit 1.4.2_08</li> <li>• Apache Tomcat (5.0.30)</li> </ul>	<ul style="list-style-type: none"> <li>• SUN Solaris 10.5 or IBM AIX 5 or HP/UX 11 or Linux</li> <li>• WebSphere</li> <li>• WebLogic</li> <li>• Tomcat</li> </ul>
<b>Server Hardware Platform</b>	<ul style="list-style-type: none"> <li>• Intel Xeon E5-2650v2 8-Core (2.60GHz 20MB)</li> <li>• Memory: at least 4 GB PC3L-12800 DDR3 1600MHz RDIMM</li> <li>• Hard Disk 128 GB 6G 10K rpm SAS SFF</li> <li>• 146GB Raid-5</li> </ul>	<ul style="list-style-type: none"> <li>• SUN VSeries or IBM PSeries or HP9000 or Intel-Xeon server</li> </ul>
<b>Workstation Software</b>	<ul style="list-style-type: none"> <li>• Internet Explorer 8</li> <li>• Adobe Acrobat Reader 9.34</li> <li>• Windows 8, Windows XP Pro or Windows 7</li> </ul>	Microsoft Windows 2000 or Windows XP or Vista
<b>Workstation Hardware Platform</b>	<ul style="list-style-type: none"> <li>• 1.5 GHz processor (Intel Core i3 processor)</li> <li>• 1 GB of RAM</li> <li>• 40 GB hard disk</li> </ul>	<ul style="list-style-type: none"> <li>• Pentium III or IV</li> <li>• Ethernet compatible or wireless network</li> <li>• Touch Screen: ELO ET 1715L</li> <li>• PDA: Symbol/Motorola MC3090</li> <li>• Signature Table: TOPAZ Systems model T-L462-HSB</li> <li>• Fingerprint: Yubee DPL 1037000YB</li> <li>• Barcode scanner: Metrologic MS 9520</li> </ul>
<b>Platforms</b>	Open industry standard	Open industry standard
<b>Technology</b>	J2EE web based	J2EE web based
<b>Interfaces</b>	None	<ul style="list-style-type: none"> <li>• National Deferred Donor Register</li> <li>• LIMS</li> </ul>

## 510(k) Summary for e-Delphyn Blood Management Software

	<b>Subject Device</b> e-Delphyn Blood Management Software Version 7.1.0.0	<b>Predicate</b> ePROGESA 5.0.1 BK080002
		<ul style="list-style-type: none"> <li>• Laboratory Instrument</li> </ul>
<b>Donor recruitment</b>	No	Yes
<b>Donor Identification</b>	Donor demographics	Digitized tablet to capture donor signatures and donor photographs
<b>Pre donation activities</b>	Donor registration Donor eligibility Recording vitals Donor deferral	Donor administration
<b>Donation Activities</b>	Management of collection of blood components and apheresis products for autologous and allogeneic donations.	Collection administration including donor eligibility status (Blood, Plasma, Platelets, Cord Blood)
<b>Components</b>	Preparation, manufacturing, testing, labeling	Preparation and transformation with process documentation
<b>Donor Product Management</b>	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.
<b>Barcodes Supported</b>	ISBT 128	ISBT 128
<b>Product</b>	Inventory management, delivery/shipping, product returns	Inventory management, delivery/shipping, product returns
<b>Use of Wireless Technology</b>	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.

#### **Clinical Testing (External Validation Testing):**

External Validation Testing (Beta) was performed at two (2) beta sites that included a total of 1943 test cases.

## 510(k) Summary for e-Delphyn Blood Management Software

### **Conclusion:**

There are no open anomalies known for e-Delphyn Blood Management Software version 7.1.0.0 for which this 510(k) is submitted.

The successful non-clinical testing and clinical testing (external validation testing) demonstrates the safety and effectiveness of the Hemosoft e-Delphyn when used for the defined intended use and demonstrates that the device for which the 510(k) is submitted performs as well as the legally marketed predicate device.