

510(k) Summary for e-Delphyn LIS Donor

Submitter's Name	Hemasoft Software, S.L.
Address	Antonio Lopez 249, 4º, 28041 Madrid, Spain
Establishment Registration Number	Will register within 30 days after placing this device into commercial distribution
Date of Summary	October 23, 2020
Telephone Number	+34 91 500 10 87
Fax Number	+34 91 500 11 43
Contact Person	Pedro Pereda
Name of the Device	e-Delphyn LIS Donor
Common or Usual Name	Blood Establishment Computer Software And Accessories
Classification Name	Blood establishment computer software and accessories
Product classification	Product code: MMH C.F.R.Section: 21 CFR §864.9165 Device class: Class II
Indications for Use	e-Delphyn LIS Donor is a web enabled modular computerized system intended to be used by trained personnel to enter and evaluate test results in accordance with the decision rules as well as to manage sample storage and bacterial testing.
Identification of the Legally Marketed Device (Predicate Device)	SURROUND -Version 5.1 (Haemonetics Corporation) 510(k) BK140199 cleared February 5, 2015 Blood Establishment Computer Software And Accessories Device Class: Class 2 Product Code: MMH

510(k) Summary for e-Delphyn LIS Donor

Device Description

e-Delphyn LIS Donor is a web enabled modular computerized system that is intended to be used by trained personnel to aid in the management and validation of samples (donations and external samples).

The system is built using (b) (4) technology on the front end and JAVA technology on the back end which enables the system to work from small-scale laboratory operations to multiple-site laboratories and supports the use of Information Standard for Blood and Transplant (ISBT) 128.

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

Main Module

The Main Module provides functionality for registering donations and external samples and entering and evaluating test results, by sample and by batch, in accordance with the decision rules. The Main Module also provides functionality for archiving samples; registering tube withdrawal; and registering bacterial testing.

Users Module

The Users Module provides functionality for configuring 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 LIS Donor

Intended Use Comparison

Subject Device:

e-Delphyn LIS Donor

e-Delphyn LIS Donor is a web enabled modular computerized system intended to be used by trained personnel to enter and evaluate test results in accordance with the decision rules as well as to manage sample storage and bacterial testing.

Predicate Device:

SURROUND 5.1, BK140199

Surround 5.1 is a computerized system to be used by trained personnel as an aid in the collection, collation, interfacing and management of test results and interpretations of data generated by the laboratory testing of donor and patient blood samples.

510(k) Summary for e-Delphyn LIS Donor

Device Comparison Table

	Subject Device e-Delphyn LIS Donor Version 11.0.0.1	Predicate SURROUND 5.1 BK140199
Application Language	Java (back) (b) (4) (Front)	Java **Very minimal: Microsoft Visual C++
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	Surround Core Client Server architecture Surround Web Interface (SWI) Three-tiered software architecture consisting of an Application/WebServer, a client and a relational database.
Server Software	<ul style="list-style-type: none"> • Windows Server 2016 • Java SDK Kit 1.8.0_201 • Apache Tomcat (8.5.42) 	Surround Core: <ul style="list-style-type: none"> • Windows Server 2016 • Oracle Java SE Runtime Environment (Version 1.8.0) Surround Web Interface (SWI): <ul style="list-style-type: none"> • Apache Tomcat 8.5 • Windows Server 2016 • Oracle Java SE Runtime Environment (Version 1.8.0)
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"> • Intel Xeon 2.40 GHz • 4GB RAM • Hard disk 80 GB
Workstation Software	<ul style="list-style-type: none"> • Chrome version 70.0.3538 • Adobe Acrobat Reader DC 2020.009 • Windows 7, 8 or Windows 10 	Surround Core: Windows 10 Windows 2016 Surround Web Interface (SWI): Internet Explorer 11
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"> • Intel Xeon 2.40 GHz • 2GB RAM • Hard disk 20 GB
Platforms	Open industry standard	Unknown
Technology	J2EE web based	Core Java
Interfaces	<ul style="list-style-type: none"> • Data Innovation • e-Delphyn Donor 	PRISMs and 4 Olympus PKs. The Ortho Summit Tango Blood Analyzer

510(k) Summary for e-Delphyn LIS Donor

	Subject Device e-Delphyn LIS Donor Version 11.0.0.1	Predicate SURROUND 5.1 BK140199
		Echo instrument Neo instrument Roche DOMS Immucor Galileo CHIRON NAT Tracker DiaSorin ETI-Max 3000 Ortho Assay Software Motoman AutoSorter II Specimen Processor Generic interface to most BECS system Generic interface to most file based interfaces Generic interface to most ASTM based instruments
Donor recruitment	Not applies	Not applies
Donor Identification	Not applies	Not applies
Pre donation activities	Not applies	Not applies
Donation Activities	Not applies	Not applies
Components	Testing,	Laboratory Communication Automated Test Transfer Batch Viewer Billing Manual Entry Single Entry Batch Entry Retest Management Client Management Current Samples Manual Send Plate Map Creation Preaccessioning Shipping Sample Accessioning Sample Viewer Session User Administration User/Client Administration

510(k) Summary for e-Delphyn LIS Donor

	Subject Device e-Delphyn LIS Donor Version 11.0.0.1	Predicate SURROUND 5.1 BK140199
		Sort Management Confirmatory Testing Module Surround Web Interface-Create Workorder Sample Administration
Donor Product Management	Not applies	Not applies
Barcodes Supported	ISBT 128	ISBT 128 Codabar
Product	Not applies	Not applies
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 339 test cases

Clinical Testing:

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

Conclusion:

There are no open anomalies known for e-Delphyn LIS 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 LIS Donor software. The results of these activities demonstrate that the e-Delphyn LIS 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 LIS Donor software is considered substantially equivalent to the predicate device.