

FIFTH DIMENSION INFORMATION SYSTEMS**SPI – System for Plasma Identification**

SPI-FDA-0013.3

Title: SPI 2.0.0 510(k) Summary

Effective Date: Sep 07, 2005

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510(k) Summary of Safety and Effectiveness

Substantially Equivalent 510(k) Device Information:

Applicant: Fifth Dimension Information Systems, A HAEMONETICS® Company on behalf of ZLB Behring AG

Product: SPI-System for Plasma Identification, version 2.0.0

Date: Oct 31, 2005

Summary of Safety and Effectiveness

Classification Name: Unclassified, Product Code MMH
Product Trade Name: SPI version 2.0.0
Common Name: Blood Establishment Computer Software

Predicate Device:

The SPI 2.0.0 system is substantially equivalent to its previously submitted version, System for Plasma Identification (SPI) version 1.0 (510(k) number-BK020020), cleared on October 30, 2002.

Device Description:

Like the predicate device, SPI is a software application used to organize and control the transport of plasma from collection facilities to fractionators.

The features of SPI are as follows:

1. Center

- Upload unit, carton and shipment information through interface from collection facility data systems via electronic interface.
- Create unit, carton and shipment information manually as necessary.
- Identify and assign ancillary shipment contents, supplies and test kits.
- Specify shipping statements as required by the fractionator to receive shipments processed.
- Format and generate carton identification and shipping labels.
- Record and resolve unit, carton and shipment discrepancies.
- Create and iterate the status of post donation information notes.
- Create staff members eligible to access the Center module of SPI.

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- Restrict shipment from center based on minimum testing requirement.
2. Consignee
 - Receive shipments from collection facilities.
 - Raise and report shipment and carton discrepancies.
 - Load cartons into containers designed and prepared by the fractionator.
 - Generate shipping documentation.
 - Process shipments to fractionator.
 - Report and investigate container discrepancies.
 3. Fractionator
 - Design containers to be loaded by and received from consignees.
 - Consolidate shipments received from consignees.
 - Receive shipments from consignees and verify containers received.
 - Scan shipments into bins manually or via conveyor.
 - Label and sequence pools.
 - Transfer shipments, cartons and bins between storage locations.
 - Receive and follow post donation information notes to resolution.
 - Design pools and pool plasma as required.
 - Receive test results and resolve associated discrepancies.
 4. Testing Laboratory
 - Electronically receive test result information from testing laboratories.

Intended Use:

The System for Plasma Identification (SPI) is designed to provide collection facilities with the ability to directly communicate shipment information to their fractionator and to provide the fractionator with a control and communication mechanism that allows the fractionator to determine the flow of plasma shipments from a range of collection facilities, communicate post donation information to their collection facilities and sort, warehouse and pool the plasma it receives.

Technological Characteristics:

The SPI 2.0.0 system is technologically similar to the predicate device. It utilizes the same software architecture, and is operated on the same database as SPI 1.0.

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Summary of Safety and Efficacy:

SPI version 2.0.0 has been validated. A hazard analysis has been developed and all hazards identified have been mitigated. Like the predicate device, SPI is safe and effective for its intended use.