Eva D. Quinley, MS, MT(ASCP)SBB, CQA(ASQ)
Sr. Director, Regulatory Affairs & Laboratory Operations

CSL Plasma
1001 Corridor Park Blvd.
Knoxville, TN 37934

Tel 1-865-766-1406
Fax 1-865-218-4599
eva.quinley@cslplasma.com

CSL Plasma

CSL Plasma, Inc LOGIC 4.0.8 510(k) Summary

Date Prepared: September 29, 2021

Submitter: CSL Plasma, Inc.
900 Broken Sound Parkway, Suite 400
Boca Raton, FL 33487
United States

Official Correspondent: Eva D. Quinley, MS, MT(ASCP)SBB, CQA(ASQ)
Sr Director Regulatory Affairs and Laboratory Operations
Cell: 865-766-1406

Trade Name: LOGIC 4.0.8
Classification Name: Automated Blood Grouping and Antibody Test System
Common Name: Blood Establishment Computer Software
Product Code: MMH
Regulation Number: 21CFR 864.9165

Predicate Device:
Device Classification Name: Automated Blood Grouping and Antibody Test System
510(k) Number: BK120002
Device Name: LOGIC 3.0
Original Applicant: CSL Plasma, Inc.
Product Code: MMH
Regulation Number: 21CFR 864.9165
Decision Date: June 08, 2011
Decision: Substantial equivalent (SE)
Type: Traditional

Device Description:

LOGIC 4.0.8 is a web-based software application used to support daily operations of product logistics, primarily organizing and controlling the movement of plasma units between facilities such as warehouses and fractionators. The application also communicates observations or post donation information, status and recalls between collection, warehouse and fractionation facilities. LOGIC provides interface capabilities with sub-systems.

Detailed features of LOGIC 4.0.8 are:

- Receive unit, sample, container (e.g., carton), pallet, and shipment information through an interface from collection facility data systems

- Receive shipments from facilities and verify containers or pallets received
- Place and manage orders for product
- Format and generate container and pallet labels
- Generate shipping documentation such as packing lists and bill of lading
- Specify shipping statements including testing statements as required by the fractionators to receive shipments for processing
- Create and send shipments to facilities such as fractionators and warehouses
- Create and report unit, container, pallet and shipment discrepancies
- Create and manage the status of observations and post donation information to resolution (e.g., destruction)
- Prevent unsuitable units from shipping through use of configurable shipment release rules
- Move pallets and containers between storage locations within a facility (inventory management).
- Record pool and manufactured lot information
- Receive observations, lookback, test results, and unit applicant status through interfaces from external data systems
- Generate shipment information to be sent to external systems
- Secure internal controls via the assignment and configuration of security roles and the creation of users who are authorized to access LOGIC

Indications for Use:

Intended Use for Predicate Device: The intended use of LOGIC 3.0 is to organize and control the transport of units between facilities such as collection sites, warehouses and fractionators. LOGIC also communicates observations or post donation information, status and recalls between collection, warehouse and fractionation facilities.

Intended Use for LOGIC 4.0.8: The intended use of LOGIC is to organize and control the transport of units between facilities such as collection sites, warehouses and fractionators. LOGIC also communicates observations or post donation information, status and recalls between collection, warehouse and fractionation facilities. LOGIC provides interface capabilities with sub-systems.

Device Comparison Table:

Parameter/Character	Subject Device LOGIC 4.0.8	Predicate Device LOGIC 3.0 (BK120002)
Programming Language	Frontend: HTML5, SCSS, Angular, Bootstrap, and TypeScript Backend: Node.js, TypeScript, and SQL Database: PL/SQL	PL/SQL
Database	Oracle DBMS	Oracle DBMS
Application Server OS	Linux	Windows 2008 Server
Database Server OS	Oracle Linux	HPUX
Client OS	Windows 10	Windows XP
Client Workstation Hardware	PC/Laptop/Virtual Desktop Infrastructure	PC

Technological Characteristics:
As described in the table above, both applications are based on an Oracle database. While programming development technologies are different, both utilize similar Oracle-based languages.

Substantial Equivalence:

The proposed LOGIC 4.0.8 application is substantially equivalent to the legally marketed LOGIC 3.0 application in intended use, features and technological characteristics.

Both systems provide management controls and information services that have been designed to assist personnel in the operation of a plasma center. These controls include:

- Receive unit, sample, container (e.g., carton), pallet, and shipment information through an interface from collection facility data systems
- Receive shipments from facilities and verify containers or pallets received
- Place and manage orders for product
- Format and generate container and pallet labels
- Generate shipping documentation such as packing lists and bill of lading
- Specify shipping statements including testing statements as required by the fractionators to receive shipments for processing
- Create and send shipments to facilities such as fractionators and warehouses
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- Secure internal controls via the assignment and configuration of security roles and the creation of users who are authorized to access LOGIC

Non-Clinical Testing:

Based upon non-clinical testing, the LOGIC Version 4.0.8 device was found to be safe for its intended use and is substantially equivalent to the predicate device in terms of intended use, functionality, technological characteristics as well as safety and effectiveness.