Life Plasma, Inc.
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5. 510(k) Summary

In accordance with 21 CFR 807.87(h), a 510(k) Summary is included that meets the conditions as outlined for a 510(k) summary in 21 CFR 807.92.

Submitter Information:

510(k) Owner/Submitter: Life Plasma, Inc.

Official Correspondence regarding this 510(k):

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FEI: 3021916912

Proposed Device Information:

Trade Name: SmartDMS 1.0.0 (Life Plasma, Inc.)

Common Name: Blood Establishment Computer Software (BECS)

Product Code: MMH

Device: Stand-alone Blood Bank Software

Review Panel: Hematology

Device Class: Class II

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Predicate Device Information:

Predicate	Trade Name	Manufacturer	510(k) Number	Classification Product Code
Predicate-1	GDS 1.0 (Grifols Donation System)	Biomat USA, Inc.	BK180240	MMH
Predicate-2	NextGen 3.0.0	Haemonetics Corporation Software Solutions	BK150330	MMH
Predicate-3	ePROGESA 5.0.1	MAK-System SAS International Group	BK080002	MMH

Device Description:

The proposed Smart Donor Management System (SmartDMS) version 1.0.0 is a Blood Establishment Computer Software (BECS) that assists in the management of donors and blood products. The software automates the processes of a Source Plasma center. The system manages the donor visits, records the donations, tracks test samples and results, and manages the shipment of units out of the center. The device includes many safety checks to ensure donor suitability and unit releasability requirements are met.

Intended Use:

Smart DMS is a BECS used in Source Plasma donation centers. The device assists in the management of data related to donors, their suitability to donate, collection of Source Plasma, product testing, storage, manufacturing, and shipping.

Indications for Use:

SmartDMS is a stand-alone BECS that is used to capture medical screening information, donor health assessment, capturing donation details, donor status management and for lookback capabilities. Additionally, SmartDMS is also used to capture lab testing results, barcode scanning, quality assurance, inventory, shipping, and product release. The SmartDMS operates as a stand-alone system and does not interface or interfere with the apheresis device or software.

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SmartDMS interfaces with PPTA's National Donor Deferral Registry (NDDR) and Cross-Donation Check System (CDCS).

Substantial Equivalence:

The proposed software device, SmartDMS 1.0.0, is substantially equivalent to the software devices GDS 1.0 (Predicate-1), NextGen 3.0.0 (Predicate-2) and ePROGESA 5.0.1 (Predicate-3).

The proposed SmartDMS 1.0.0 uses similar technology as its predicate devices. While there are minor differences in technological characteristics and principles of operation between the proposed device and its predicate devices, none of these differences raise new types of safety or effectiveness questions. This demonstrates that the technology used in the proposed SmartDMS 1.0.0 software device is substantially equivalent to the technology used in one or more of the predicate devices.

The proposed SmartDMS 1.0.0 software device and its predicates are equivalent to or the same with respect to mapped intended use, functionality, performance, and technological characteristics, as well as safety and effectiveness.

Clinical Trials

Clinical performance testing is not applicable for Smart DMS 1.0.0, as it is a software only product.

Conclusion:

The proposed device, SmartDMS 1.0.0, was developed in accordance with 820.30 Design Controls as well as the "*FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005).*" The software was thoroughly tested including verification, validation, and user acceptance testing to ensure it is as safe, as effective, and performed as well as each predicate device`s functionality, when utilized within its intended use and in accordance with labeling, as demonstrated by the testing performed.

Based on the functionality and performance comparison, technological characteristics comparison and the intended use, the proposed Smart DMS 1.0.0 device performs as intended in all aspects of the predicate devices mapped functionality characteristics. The safety aspects of the proposed Smart DMS 1.0.0 device have been thoroughly tested in accordance with validation practices as outlined in 820.30, Design Controls. The proposed Smart DMS 1.0.0 software device is substantially equivalent to the predicate devices in terms of intended use, functionality, performance, technological characteristics as well as safety and effectiveness.