Biomat USA, 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.

Date: 22 OCT 2018

Submitter Information:

510(k) Owner/Submitter: Biomat USA, Inc.

Official Correspondence regarding this 510(k):

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Establishment Registration Number: 3005488132

Device:

Device Classification Name:	**Software, Blood Bank, Standalone Products**
Trade Name:	**GDS version 1.0 (Grifols Donation System)**
Common Name:	**Donor Center Computer Software**
Review Panel:	**Hematology**
Classification Product Code:	**MMH**
Device Classification Regulation:	**21 CFR 864.9175**
Device Class:	**Class II**
MDUFA PIN:	**MD6100007**

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Predicate Device:

	Trade Name	Manufacturer	510(k) Number	Classification Product Code
Predicate 1	Donor Management System (DMS) 1.0.0	Original Applicant: Fifth Dimension Information Systems; now, Haemonetics Corporation Software Solutions	BK990022	MMH
Predicate 2	NextGen 3.0.0	Haemonetics Corporation Software Solutions	BK150330	MMH
Predicate 3	ePROGESA – Version 5.0.1	MAK-System SAS International Group	BK080002	MMH

Device Description and Intended Use

GDS (acronym for Grifols Donation System), version 1.0, is an application designed to manage plasma donor center activities such as donor eligibility, unit suitability, shipments (units and samples), and sample management. GDS software provides management controls and information services modules that have been designed to assist personnel in the operational core functions in the company's plasma donor centers.

GDS medical device functions by modules:

- **Donor Registration**: processes donor registration data and schedules donor visits. This module records and tracks essential and mandatory donor checks applied to a donor during the registration process before considering further processing.
- **Donor Assessment**: manages a series of processes that are used to determine donor eligibility that include the administration, recording, and tracking of various screening tests, medical questionnaires, consent agreements, and medical evaluations. In addition, it has the capability to receive information from a Computer Assisted Self-Interview (CASI) system.
- **Phlebotomy and Unit Processing**: records the results of the plasmapheresis process in the GDS system, as well as any deviation (i.e., collection incident) that occurred during the collection process.
- **Inventory and Shipment**: manages the tasks required to handle units from the moment they are collected until they are shipped/released; which includes unit packing and shipment staging & verification. It also includes:
    - o inventory management tools designed to update unit information, determine the Unit Release Status automatically, based on information received/entered in the application;

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  - capture, track/report unsuitable units at the center;
  - track/report lookbacks (i.e., units implicated on a post donation event that are no longer at the center).
- **Samples Management**: includes the tasks required to collect and ship samples, receive test results, and decide on donor and unit status based on test results.
- **Special Plasma Programs**: management of specific collection and donor immunization programs.

Technological Characteristics

The proposed GDS version 1.0 computer software system is substantially equivalent to the legally marketed devices Donor Management System (DMS) version 1.0.0 (Predicate 1), NextGen version 3.0.0 (Predicate 2), and ePROGESA version 5.0.1 (Predicate 3), in intended use, features, and technological characteristics.

All four software devices provide management controls and information service modules that have been designed to assist personnel in the operation of donor center core functions including, but not limited to, donor registration, donor eligibility assessment, unit suitability, inventory and shipment, samples management, supplies management, equipment maintenance, and quality management.

GDS version 1.0 application is based on Oracle Database, Oracle ADF, Java development technologies and PL/SQL, running on a Weblogic Server and RedHat platform, and designed for Internet Explorer. NextGen and ePROGESA predicate devices also use Java development technologies while DMS predicate device is based on PL/SQL development technologies. All three predicate devices are based on Oracle Database and use similar technology in operating system and hardware. The differences in technological characteristics and principles of operation among the systems do not pose device safety or effectiveness concerns.

Clinical Trials

Clinical performance testing is not applicable for GDS version 1.0, as it is a software only product.

Summary of Safety and Effectiveness

The GDS version 1.0 device was developed in accordance with relevant regulations. The software was thoroughly tested including verification, user acceptance testing and validation to ensure that the system was properly developed and functions in accordance with its intended use.

Based on the testing results and the functional and technological comparison, the GDS version 1.0 device is safe for its intended use and it is substantially equivalent to the predicate devices in terms of intended use, functionality, technological characteristics as well as safety and effectiveness.