November 5, 2018

Biomat USA, Inc.
Attention: Mr. Charles E. Auger
2410 Lillyvale Avenue
Los Angeles, CA 90032-3514

Re:	BK180240
Trade/Device Name:	GDS (Grifols Donation System), version 1.0
Regulation Number:	21 CFR 864.9165
Regulation Name:	Blood Establishment Computer Software and Accessories
Regulatory Class:	Class II
Product Code:	MMH
Dated:	October 31, 2018
Received:	October 31, 2018

Dear Mr. Auger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety

reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Orieji Illoh, MD
Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Enclosure
Indications for Use

Indications for Use

510(k) Number: BK180240

Device Name: GDS (Grifols Donation System)

Indications for 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:
    - Inventory management tools designed to update unit information, determine the Unit Release Status automatically, based on information received/entered in the application;
    - 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.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CBER, Office of Blood Research and Review

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Division Sign-Off, Office of Blood Research and Review