March 10, 2021

International Biophysics Corporation
Geoff Marcek
VP Engineering and Quality
2101 E. St. Elmo Road
Austin, Texas 78744

Re: K193663
Trade/Device Name: FloPump 57mL Centrifugal Pump
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller-Type Blood Pump
Regulatory Class: Class II
Product Code: KFM
Dated: February 4, 2021
Received: February 5, 2021

Dear Geoff Marcek:

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 (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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Fernando Aguel
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193663

Device Name
FloPump 57mL Centrifugal Pump

Indications for Use *(Describe)*
The FloPump 57mL Centrifugal Pump is a device that uses a method other than revolving rollers to pump the blood through an extracorpreal circuit for periods lasting less than 6 hours for the purpose of providing either:

i) Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or

ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date: November 19, 2020

Manufacturer:
International Biophysics Corporation
2101 E. St. Elmo Road
Austin, TX 78744

Contact Person:
Geoff Marcek
VP, Engineering and Quality
Phone: (512) 814-0046
Email: gmarcek@biophysics.com

Product	Classification	Product Codes
FloPump 57mL Centrifugal Pump	Class II	KFM

Product Code	Regulation and Classification Name
KFM	Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type per 21 CFR 870.4360

Description:

The FloPump 57mL is a single use disposable centrifugal pump head. The pump has an inlet that draws blood from a patient and an outlet that pushes the blood out, where it then passes through an oxygenator and back to the patient. The pump mates with the Sorin Group Stöckert Centrifugal Pump Console and rotates the internal impeller using a magnetic driver. The FloPump 57mL is a non-occlusive pump. The pump has a spinning rotor with flow channels which imparts rotary motion to the incoming blood, directing it through a spiral housing to the outflow port. The FloPump 57mL is part of the extracorporeal circuit, and is therefore in contact with the patient's blood while circulating. The FloPump 57mL does not have any other patient contact.

Specifications:

Model Numbers	6500S (Sterile), 6500N (Non-Sterile)
Priming Volume	Approx. 57 mL
Inlet/Outlet I.D.	9.5mm (3/8")
Max. rated pressure	750 mmHg
Flow rates	0 – 7 L/min
Materials	
Pump Housing	Polycarbonate
Impeller and Magnet Housing	ABS
Bearings	HDPE
Shaft	Stainless steel
Magnet	Nylon NdFeB Blend

Indications for Use:

The FloPump 57mL Centrifugal Pump is a device that uses a method other than revolving rollers to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either:

i) Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or

ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

Primary Predicate Device: Sorin Revolution Blood Pump – K011835

Reference Devices: IBC FloPump Centrifugal Pump – K983272
IBC FloPump 32 Centrifugal Pump – K170029

Comparable Features to Predicate Device(s): This device is comparable to the predicate devices in indications, material, design features, specifications, manufacturing methods, raw materials, intended use, packaging, labeling and sterilization.

Key Differences in Subject Device to Predicate: There are no key differences between the subject device and the predicate. The subject device has been designed and constructed to have the same technological characteristics as the predicate.

Non-Clinical Testing:

The following non-clinical testing was performed to determine substantial equivalence:

Testing	Results Summary
Flow curves	Substantially equivalent to predicates
Heat generation	Substantially equivalent to predicates
Prime volume	Substantially equivalent to predicates
Air handling	Substantially equivalent to predicates
Hemolysis	Substantially equivalent to predicates
Reliability	Substantially equivalent to predicates
Biocompatibility	Substantially equivalent to predicates
Sterilization	The sterilization process results in a SAL of 10^{-6}
Packaging durability	No signs of damage and functioned as intended following testing
Shelf-life	No signs of damage and functioned as intended following testing

Clinical Testing: Clinical testing was not required