May 3, 2023

Flosonics Medical
Caleb Chin
Senior Director, Operations
325 Front St W, Floor 4
Toronto, Ontario M5V 2Y1
Canada

Re: K223843
Trade/Device Name: FloPatch FP120
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: April 3, 2023
Received: April 4, 2023

Dear Caleb Chin:

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,

Robert T. Kazmierski -S

for

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

The item numbers included in the scope of this submission are as follows:

Description	Item Number
FloPatch FP120	FloPatch FP120

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223843

Device Name
FloPatch FP120

Indications for Use *(Describe)*
The FloPatch FP120 is indicated for use for the noninvasive assessment of blood flow in the carotid artery. FloPatch FP120 operates in a single mode, the Continuous Wave (CW) mode, and is not capable of operating in any other mode.

The device is intended to be used by medical professionals, such as physicians and nurses, in hospitals and professional environments. The device is intended for prescription use on adults only.

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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SECTION 5 – 510(k) Summary

1. Submitter Information

Submitter:	Flosonics Medical
Address:	325 Front St W, Floor 4 Toronto, ON Canada M5V 2Y1
Telephone:	1-289-998-2982
Contact:	Caleb Chin
Date Prepared:	January 24, 2023

2. Device Information

Trade Name:	FloPatch FP120
Common Name:	Cardiovascular Blood Flowmeter
Classification:	Class II per CFR 870.2100
Classification Name:	Cardiovascular blood flowmeter
Product Code:	DPW

3. Purpose of Submission

The purpose of this submission is to gain clearance for reprocessing of “Single-Use Only” devices.

4. Predicate Device Information

510(k) No.	Device	Manufacturer
K222242	FloPatch FP120	Flosonics Medical

5. Device Description

The FloPatch (FP120) is a non-invasive blood flow detection device to be used in a medical/hospital setting for use by a medical professional. The device uses ultrasound and the Doppler effect to assess the flow of blood. The device consists of a signal processing unit and an adhesive strap. The device transmits ultrasonic waves from the ultrasonic transducer to a peripheral vessel such as the carotid artery. The Doppler shifted ultrasonic waves are reflected by moving blood cells back to the ultrasonic flow transducer. The reflected signal is received by the signal processing unit which outputs the Doppler signal wirelessly to a mobile medical application. The mobile medical application then processes the Doppler signal and displays a Max Velocity trace, Max VTI (Velocity Time Integral) and the Corrected Flow Time.

6. Intended Use

The FloPatch FP120 is indicated for use for the noninvasive assessment of blood flow in the carotid artery. FloPatch FP120 operates in a single mode, the Continuous Wave (CW) mode, and is not capable of operating in any other mode.

The device is intended to be used by medical professionals, such as physicians and nurses, in hospital and professional environments The device is intended for prescription use on adults only.

7. Comparison of Technological Characteristics

This modification does not alter the device's fundamental scientific technology in comparison to the predicate device (K222242) and therefore has the same technological characteristics.

8. Performance Data

This submission is for modifications to the FloPatch FP120 cleared in 510(k) K222242.

The following tests were performed to demonstrate the substantial equivalence of the modified device to its predicate.

Test	Brief Description	Result
Simulated Use Cycles	Verified that the device can be reprocessed up to six cycles (consisting of soiling, cleaning and disinfection).	Pass
Manual Cleaning	Validate a manual cleaning process during the reprocessing of the FloPatch FP120.	Pass
Low Level Disinfection	Validate a low level disinfection process during the reprocessing of the FloPatch FP120.	Pass
Acoustic Output	Verified that repeated reprocessing does not adversely affect the acoustic output of the transducer.	Pass
Transducer Performance	Verified that repeated reprocessing does not adversely affect transducer performance characteristics • Velocity Accuracy • Flow Velocity and Depth	Pass
Physical Integrity	Verified that repeated reprocessing does not adversely affect the physical integrity of the FloPatch FP120.	Pass

Cumulative Runtime	Verified that repeated reprocessing does not adversely affect the battery runtime	Pass

9. Conclusion

Based on the indications for use, technological characteristics, performance testing and comparison to the predicate device, the FloPatch FP120 has been shown to be substantially equivalent to the legally marketed predicate device identified in this submission and does not present any changes to safety or effectiveness.