December 9, 2022

Flosonics Medical
Caleb Chin
Director of Quality and Regulatory
325 Front St W, Floor 4
Toronto, Ontario M5V 2Y1
Canada

Re: K222242
Trade/Device Name: FloPatch FP120
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: October 20, 2022
Received: November 7, 2022

Dear Mr. 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

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

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)*
K222242

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:	July 19, 2022

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 product modifications to the previously cleared device.

Product modifications include:

- Adhesive material
- Device packaging
- Software including but not limited to:
  - Addition of a Guided Assessment workflow with smart window algorithm
  - New software features
  - Signal Processing Algorithm Changes
- Instructions for use to update acoustic output values

4. Predicate Device Information

510(k) No.	Device	Manufacturer
K200337	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 to Predicate Device

Feature/ Characteristic	FloPatch (FP120) [Subject Device]	FloPatch (FP120) Primary Predicate [K200337]
Class/Classification/Product Code	Class II/DPW (21 CFR 870.2100 Cardiovascular blood flowmeter)	Same
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 hospitals and professional environments. The device is intended for prescription use on adults only.	Same
Indications for Use	Identical to Intended Use	Same
Intended Users	Medical professionals such as Physicians and Nurses	Same
Use environment	Hospitals and professional environments such as clinics and doctor's offices.	Same.
Patient Population	Adults, ages 18 years and older	Same
Intended for Prescription Use	Yes	Same
Installation and Use	Body Worn	Same
Theory of Operation	Use of the Doppler effect to evaluate the flow velocity of blood in peripheral vasculature.	Same
Center Frequency	4 MHz	Same
Global Maximum Outputs/Worst Case Setting	Max ISPTA.3 (mW/cm2) - 172.05 Max MI - 5.22E-02	Max ISPTA.3 (mW/cm2) - 15.78 Max MI - 1.11E-02

Modes of Operation	One mode, continuous	Same
Reusable	No, the device is single use for a single patient.	Same
Dimensions	With adhesive Height 114 mm Width 70 mm Depth 32 mm Without Adhesive Height 54mm Width 35 mm Depth 18 mm	With adhesive Height 200 mm Width 65 mm Depth 30mm Without Adhesive Height 54mm Width 35 mm Depth 18 mm
Weight	22 gms	Same
The degree of protection against harmful ingress of liquid	IP67	IPX7
Type of Power Source	LiPo Battery (IEC 62133 certified)	Same
Battery Operating Voltage	4.2 V for the battery	Same
Battery Chemistry	Lithium Polymer	Same
The degree of protection against electric shock	Type BF (Defibrillation Protected)	Type B (Defibrillation Protected)
Buttons	One Power Button on FloPatch FP120 hardware	Same
Status LED	One, power and battery Indicator	Same
Onboard Screen	None - Multi Touch Mobile Medical Application screen	Same
Displays Doppler Waveform	Yes	Same
Displays Max Velocity Waveform	Yes	Same
Displays VTI Calculation	Yes	Same
Displays Corrected Flow Time Calculation	Yes	Same
Displays Peak Systolic Velocity	Yes – in a different form	Yes

Wireless Mobile Application	Yes	Same
Calibration Required	No	Same
Maintenance	Single-use device	Same
Contact Classification	Surface Device, Intact Skin Contacting, Contact Duration: <24 hrs	Same
Electrical Safety	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR.2:2007 + A1:2012	Same
EMC	IEC 60601-1-2:2014	Same
Ultrasound Basic Safety and Essential Performance	IEC 60601-2-37:2015	Same
Biocompatibility	ISO 10993-1, -5, -10, -12	Same

8. Performance Data

This submission is for modifications to the FloPatch FP120 cleared in 510(k) K200337.

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

Test	Brief Description	Result
EMC	Verified that the device meets Class B requirements. CISPR B	Pass
Biocompatibility	Verified that the adhesive met biocompatibility requirements	Pass
Material and Shelf Life Test	Verified and validated that the adhesive satisfies performance testing	Pass
Packaging Test	Verified that the packaging met ISTA3 and performance testing	Pass
Electrical Safety Testing	Verified that the device meets applied part BF requirements	Pass

Software Testing • Display Metrics • Flow Accuracy and Depth • Velocity Accuracy • Saved Measurement • Unit • Appearance • Session Length	Verified that the software application satisfies functional requirements and performs as intended. Algorithms and calculations were also verified.	Pass
Dust Ingress Testing	Verified that the device met IP6X dust ingress requirements	Pass
Emergency Services Equipment Testing	Verified the device met transport medical equipment requirements. • Shock testing • Vibration testing • Free fall testing	Pass
Acoustic Output (Track 3)	Verified that global maximum derated ISPTA ≤720 mW/cm2 and the global maximum MI should be ≤ 1.9	Pass
Ultrasound Safety	Verified that the device meets IEC 60601-2-37	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.