June 20, 2025

Flosonics Medical
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K251114
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 11, 2025
Received: April 11, 2025

Dear Prithul Bom:

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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

for Robert T. Kazmierski -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251114

Device Name

FloPatch FP120

Indications for Use *(Describe)*

The FloPatch FP120 is indicated for use for the noninvasive assessment of blood flow in peripheral vasculature. FloPatch FP120 operates in a single mode, the Continuous Wave (CW) mode only.

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.

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:	November 2, 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 product modifications to the previous cleared device.

Product modification include:

- Device Indications for Use
- Adhesive Material
- Shelf Life
- Hardware Changes
  - Ultrasound Transducer
  - Electronics
  - Enclosure
- Software including but not limited to:
  - Algorithm changes
  - User Interface changes
  - Logging of system and device metrics

4. Predicate Device Information

510(k) No.	Device	Manufacturer
Primary: K223843	FloPatch FP120	Flosonics Medical
Reference: K191388	FloPatch FP110	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. 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 peripheral vasculature. FloPatch FP120 operates in a single mode, the Continuous Wave (CW) mode only.

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 Devices

Feature/ Characteristic	FloPatch (FP120) [Subject Device]	FloPatch (FP120) Primary Predicate [K223843]	FloPatch (FP110) Reference Device [K191388]
Class/Classification/ Product Code	Class II/DPW (21 CFR 870.2100 Cardiovascular blood flowmeter)	Same	Same
Intended Use	The FloPatch FP120 is indicated for use for the noninvasive assessment of blood flow in peripheral vasculature. FloPatch FP120 operates in a single mode, the Continuous Wave (CW) mode only.	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	The FloPatch (FP110) is intended for the detection of blood flow in peripheral vasculature. The device is intended to be used by medical professionals such

	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.	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.	as physicians and nurses, in hospitals and professional environments. The device is intended for prescription use only.
Indications for Use	Identical to Intended Use	Same	Same
Intended Users	Medical professionals such as Physicians and Nurses	Same	Same
Use environment	Hospitals. professional environments such as clinics and doctor's offices.	Same	Same
Patient Population	Adults, ages 18 years and older	Same	Same
Intended for Prescription Use	Yes	Same	Same
Installation and Use	Body Worn	Same	Same
Theory of Operation	Use of the Doppler effect to evaluate the flow velocity of blood in peripheral vasculature.	Same	Same
Center Frequency	4 MHz	Same	Same
Global Maximum Outputs/Worst Case Setting	Max ISPTA.3 (mW/cm2) – 53.58 Max MI – 3.09E-02	Max ISPTA.3 (mW/cm2) – 105.99 Max MI - 3.76E-02	Max ISPTA.3 (mW/cm2) – 720 Max MI – 1.9
Modes of Operation	One mode, continuous	Same	Same
Reusable	No, the device is single use for a single patient.	Same	Same

Dimensions	With adhesive Height 145 mm Width 76 mm Depth 32 mm Without Adhesive Height 54 mm Width 35 mm Depth 14 mm	With adhesive Height 114 mm Width 70 mm Depth 32 mm Without Adhesive Height 54mm Width 35 mm Depth 18 mm	135 mm x 108mm x 43.3 mm
Weight	21 gms	22 gms	<450 gms (including battery)
The degree of protection against harmful ingress of liquid	IP67	Same	IPX1 for vascular flow transducer. IPX0 for enclosure
Type of Power Source	LiPo Battery (IEC 62133 certified)	Same	Internal (AA Batteries)
Battery Operating Voltage	4.2 V for the battery	Same	1.5V (single AA cell) 4.5V for battery (3 AA Cells)
Battery Chemistry	Lithium Polymer	Same	Alkaline
The degree of protection against electric shock	Type BF (Defibrillation Protected)	Same	Type B
Buttons	One Power Button on FloPatch FP120 hardware	Same	One Power Button
Status LED	One, power and battery Indicator	Same	Absent
Onboard Screen	None - Multi Touch Mobile Medical Application screen	Same	One, power and battery Indicator
Displays Doppler Waveform	Yes	Same	No
Displays Max Velocity Waveform	Yes	Same	No
Displays VTI Calculation	Yes	Same	No

Displays Corrected Flow Time Calculation	Yes	Same	No
Displays Peak Systolic Velocity	Yes	Same	No
Wireless Mobile Application	Yes	Same	No
Calibration Required	No	Same	Same
Maintenance	Single-use device	Same	Same
Contact Classification	Surface Device, Intact Skin Contacting, Contact Duration: <30 days	Surface Device, Intact Skin Contacting, Contact Duration: <24 hrs	Limited Contact Duration (<24 hrs), Intact Skin, Surface Device
Electrical Safety	IEC 60601-1:2005+A1:2012+A2:2020	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR.2:2007 + A1:2012	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR.2:2007 + A1:2012
EMC	IEC 60601-1-2:2014+A1:2020	IEC 60601-1-2:2014	IEC 60601-1-2:2014
Ultrasound Basic Safety and Essential Performance	IEC 60601-2-37:2015	Same	Same
Biocompatibility	ISO 10993-1, -5, -10, -12, -21	ISO 10993-1, -5, -10, -12	ISO 10993-1, -5, -10, -12

8. Performance Data

This submission is for modifications to the FloPatch FP120 cleared in 510(k) K223843.

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

Test	Brief Description	Result
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
Ultrasound Performance	Verified that the device meets performance and ultrasound transducer requirements	Pass
Electrical and Basic Safety Testing	Verified that the device meets IEC 60601-1 requirements	Pass
EMC	Verified that the device meets IEC 60601-1-2 requirements	Pass
Emergency Service Environment Testing	Verified that the device meets IEC 60601-1-12 requirements	Pass
Ingress Protection (IP) Testing	Verified that the device meets IP67 ingress requirements	Pass
Material and Shelf Life	Verified and validated that the adhesive and device enclosure satisfies performance requirements	Pass
Usability Testing	Validated that the device meets new indications for use	Pass
Hardware Testing	Verified that the device meets mechanical and electrical requirements	Pass
Software Testing • Flow Accuracy and Depth • Saved Measurement • Mobile Appearance	Verified that the software application satisfies functional requirements and performs as intended. Algorithms and calculations were also verified.	Pass
Biocompatibility Testing • Cytotoxicity • Sensitization • Irritation	Verified that the adhesive and device enclosure met biocompatibility requirements	Pass
Simulated Use Cycles	Verified that the device can be reprocessed (consisting of soiling, cleaning and disinfection).	Pass

Low Level Disinfection (LLD) with Visual Inspection	Validate a low level disinfection process during the reprocessing of the FloPatch FP120.	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.