April 24, 2026

Flosonics Medical
Caleb Chin
Sr. Director of Operations
325 Front St. W, Floor 4
Toronto, ON M5V2Y1
Canada

Re: K252810
Trade/Device Name: FloPatch FP120
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: September 3, 2025
Received: March 13, 2026

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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

STEPHEN C. BROWNING -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.

510(k) Number *(if known)*
K252810

Device Name
FloPatch FP120

Indications for Use *(Describe)*
The FloPatch FP120 is a wireless, non-invasive Doppler ultrasound system indicated to aid medical professionals as an adjunctive assessment in performing Critical Care Ultrasonography (CCUS) for Targeted Volume Management (TVM).

The FloPatch FP120 is indicated for use for the non-invasive assessment of blood flow in peripheral vasculature (including the carotid) in a target vessel. The device operates in a single mode, Continuous Wave (CW), providing quantitative flow metrics for arterial flow.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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:	August 25, 2025

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 modify the device's indications for use.

4. Predicate Device Information

510(k) No.	Device	Manufacturer
Primary: K251114	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. 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 a wireless, non-invasive Doppler ultrasound system indicated to aid medical professionals as an adjunctive assessment in performing Critical Care Ultrasonography (CCUS) for Targeted Volume Management (TVM).

The FloPatch FP120 is indicated for use for the noninvasive assessment of blood flow in peripheral vasculature (including the carotid) in a target vessel. The device operates in a single mode, Continuous Wave (CW), providing quantitative flow metrics for arterial flow.

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 [K252810]	FloPatch (FP120) Primary Predicate [K251114]
Class/ Classification/ Product Code	Class II/DPW (21 CFR 870.2100 Cardiovascular blood flowmeter)	Same
Intended Use	The FloPatch FP120 is a wireless, non-invasive Doppler ultrasound system indicated to aid medical professionals as an adjunctive assessment in performing Critical Care Ultrasonography (CCUS) for Targeted Volume Management (TVM). The FloPatch FP120 is indicated for use for the noninvasive assessment of blood flow in peripheral vasculature (including the carotid) in a target vessel. The device operates in a single mode, Continuous Wave (CW), providing quantitative flow metrics for arterial flow. 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.	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.

Indications for Use	Identical to Intended Use	Same
Intended Users	Medical professionals such as Physicians and Nurses	Same
Use environment	Hospitals. 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) – 53.58 Max MI – 3.09E-02	Same
Modes of Operation	One mode, continuous	Same
Reusable	No, the device is single use for a single patient.	Same
Dimensions	With adhesive Height 145 mm Width 76 mm Depth 32 mm Without Adhesive Height 54 mm Width 35 mm Depth 14 mm	Same
Weight	21 gms	Same

The degree of protection against harmful ingress of liquid	IP67	Same
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)	Same
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	Same
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+A1:2012+A2:2020	Same
EMC	IEC 60601-1-2:2014+A1:2020	Same
Ultrasound Basic Safety and Essential Performance	IEC 60601-2-37:2015	Same
Biocompatibility	ISO 10993-1, -5, -10, -12, -21	Same
Range of Validated Flow Velocities	10 – 170 cm/s	Same

8. Performance Data

Performance data demonstrates that the FloPatch FP120 can measure both forward and reverse blood flow velocities in a target vessel from 10 - 170 cm/s.

9. Conclusion

From the information provided, 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.