March 24, 2020

Flosonics Medical (r/a 1929803 Ontario Corp.)
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K200337
Trade/Device Name: FloPatch (FP120)
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: February 10, 2020
Received: February 11, 2020

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 (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,

LT 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200337

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.

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510 (k) Summary

1. Submitter Information

Company Name:	Flosonics Medical (R/A 1929803 Ontario Corp.)
Company Address:	325 Front St W., Fourth Floor OneEleven Toronto, Ontario, Canada M5V 2Y1
Company Contact:	info@flosonicsmedical.com
Contact Person:	Andrew Eibl, Director Operations and Interim Quality Manager

2. Device Identification

Trade Name:	FloPatch (FP120)
Classification:	II
Generic Device Name:	Cardiovascular Blood Flowmeter

3. Classification Name

Classification Name	Product Code	Class	Regulation Number
Cardiovascular blood flowmeter	DPW	II	870.2100

4. 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.

5. 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.

6. Indications for 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.

7. Predicate/Reference Device Identification

Predicate Device (s)	Product Code (s)	Class	Regulation Number
DMX Handheld Doppler (Primary Predicate Device) **[K183574]**	DPW	II	21 CFR 870.2100
Edan Acclarix LX8 Diagnostic Ultrasound System (Reference Device) **[K180862]**	IYN, IYO, ITX	II	21 CFR 892.1550
FloPatch FP110 **[K191388]**	DPW	II	21 CFR 870.2100

8. Comparison to Predicate Device

8.1 Comparison Table

Feature/Characteristic	FloPatch (FP120) (Subject Device)	DMX Handheld Doppler [K183574] (Primary Predicate Device)	Edan Acclarix LX8 Diagnostic Ultrasound System [K180862] (Reference Device)	FloPatch FP110 [K191388] (Reference Device)
Class/Classification/ Product Code	Class II/DPW (21 CFR 870.2100 Cardiovascular blood flowmeter)	Class II/DPW (21 CFR 870.2100 Cardiovascular blood flowmeter)	Class II/ IYN, IYO, ITX (21 CFR 892.1550) Ultrasonic pulsed doppler imaging system	Class II/DPW (21 CFR 870.2100 Cardiovascular blood flowmeter)
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	Indicated for use by qualified healthcare practitioners in primary, acute and community healthcare environments, for the non-invasive assessment of vascular blood flow to assist in diagnosis.	Diagnostic ultrasound imaging or fluid flow analysis of the human body	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 as physicians and nurses in hospitals and professional enviroments such as clinics and doctor's offices. The device is intended for prescription use only.

	environments. The device is intended for prescription use on adults only.			
Indications for 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.	Identical to Intended Use	The Acclarix AX8 Diagnostic Ultrasound System is intended for use by a qualified physician or sonographer for ultrasound evaluation. Clinical applications include: Abdominal, Gynecology (including endovaginal), Obstetric, Cardiac, Small parts (Breast, Testes, Thyroid, etc.), Urology, Musculoskeletal, Peripheral vascular, Intra-operative, Pediatric and Neonatal (including abdominal and cephalic), and Adult cephalic.	Identical to Intended Use
Intended Users	Medical professionals such as Physicians and Nurses	Indicated for use by qualified healthcare practitioners in primary, acute and community healthcare environments	Intended for use by a qualified physician or sonographer	Medical professionals such as Physicians and Nurses
Use Environment	Hospitals and professional environments such as clinics and doctor's offices.	In primary, acute and community healthcare environments	Not specified	Hospitals and professional environments such as clinics and doctor's offices.
Patient Population	Adults, ages 18 years and older	Not specified	Pediatric and Adult	Adults, ages 18 years and older
Intended for Prescription Use	Yes	Yes	Yes	Yes

Installation and Use		Body Worn	Hand-Held	Portable (laptop) Mobile Equipment	Body Worn
Theory of Operation		Use of the Doppler effect to evaluate the flow velocity of blood in peripheral vasculature.	Use of the Doppler effect to evaluate the flow velocity of blood in peripheral vasculature.	Use of the Doppler effect to evaluate the flow velocity of blood in peripheral vasculature. (Doppler mode only)	Use of the Doppler effect to evaluate the flow velocity of blood in peripheral vasculature.
Center Frequency		4 MHz	4 MHz	2.5-15.0 MHz	4 MHz
Global Maximum Outputs /Worst Case Setting	Max $I_{SPTA.3}$ (mW/ cm^2)	15.78	92	21.47	720
	Max MI	1.11E-02	Not reported	0.01	1.9
Modes of Operation		One mode, continuous	One mode, continuous	Multi-Mode, Only Doppler mode relevant to this comparison	One mode, continuous
Reusable		No, the device is single-use for a single patient.	Reusable with cleaning	Reusable with cleaning	No, single use for a single patient.
Dimensions		**With adhesive** Height 200 mm Width 65 mm Depth 30mm **Without Adhesive** Height 54mm Width 35 mm Depth 18 mm	Height 140mm (5.5") Width 75mm (3.0") Depth 30mm (1.2")	407mm(W) x388mm(L) x77mm(H)	135 mm x 108mm x 43.3 mm
Weight		22 gms	310 gms	8.6Kg (with rechargeable battery and monitor glass, without power adaptor or transducers)	<450 gms (including battery)
The degree of protection against harmful ingress of liquid		IPX7 for the device	IP20 for the main unit IPX1 for the probe tip	Console Panel: IPX1 Transducers: IPX7	IPX1 for vascular flow transducer. IPX0 for enclosure
Type of Power Source		LiPo Battery (IEC 62133 certified)	Internal (AA Batteries)	Rechargeable Lithium Ion	Internal (AA Batteries)
Battery Operating Voltage		4.2 V for the battery	1.5V (single AA cell) 4.5V for battery (3 AA Cells)	14.4V	1.5V (single AA cell) 4.5V for battery (3 AA Cells)
Battery Chemistry		Lithium Polymer	Alkaline	Lithium-Ion	Alkaline

The degree of protection against electric shock	Type B (Defibrillation Protected)	Type B (Not Defibrillation Protected)	Type BF Applied Part	Type B
Buttons	One Power Button on FloPatch FP120 hardware	Three buttons	One power button	One Power Button
Status LED	One, power and battery Indicator	None	None	Absent
Onboard Screen	None - Multi Touch Mobile Medical Application screen	LCD Screen	LCD Screen	One, power and battery Indicator
Displays Doppler Waveform	Yes	Yes	Yes	No
Displays Max Velocity Waveform	Yes	Yes (Displays Frequency instead of max velocity)	Yes	No
Displays VTI Calculation	Yes	No	Yes	No
Displays Corrected Flow Time Calculation	Yes	No	No, however it can be calculated on the device based on the data captured by the device.	No
Wireless Mobile Application	Yes.	No. Has an offline data processing software called the Huntleigh DR5 (MDDS) which can only be used with Dopplex DMX device.	No. The software and screen are integrated with the ultrasound unit.	No
Calibration Required	No	No	No	No
Maintenance	Single-use device	Reusable Device-with cleaning	Reusable Device-with cleaning	Single Use Transducer
Contact Classification	Surface Device, Intact Skin Contacting, Contact Duration: <24 hrs	Surface Device, Intact Skin Contacting, Contact Duration: <24 hrs	Not Specified	Limited Contact Duration (<24 hrs), Intact Skin, Surface Device
Electrical Safety	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR.2:2007 + A1:2012	IEC 60601-1:2005 (Third Edition) + A1:2012	IEC 60601-1 version not specified	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR.2:2007 + A1:2012

EMC	IEC 60601-1-2:2014	IEC 60601-1-2:2014	IEC 60601-1-2:2007	IEC 60601-1-2:2014
Ultrasound Basic Safety and Essential Performance	IEC 60601-2-37:2015	EN 60601-2-37:2008+A11:2011	IEC/EN 60601-2-37	IEC 60601-2-37:2015
Biocompatibility	ISO 10993-1, -5, -10, -12	ISO 10993-1	ISO 10993-1, -5, -10, -12	ISO 10993-1, -5, -10, -12

8.2 Summary of Substantial Equivalence Argument and Identification of Predicate/Reference Device

The FloPatch FP120 is a battery-operated, non-invasive medical device that utilizes ultrasound and the Doppler effect to detect blood flow in peripheral vasculature, such as the carotid artery.

The primary predicate device **DMX Handheld Doppler [K183574],** was selected because it has the same intended use and similar technological characteristics to the FloPatch FP120.

The following table summarises the rationales for selecting the predicate devices:

No.	Identified Predicate Device/Reference	Rationale for Selection
1.	**DMX Handheld Doppler [K183574] (Primary Predicate Device)**	The DMX Handheld doppler has the same intended use and indications for use as the FloPatch FP120. It can capture and automatically trace the Doppler spectrogram and calculate heart rate but does not calculate the VTI and Corrected Flow Time from the Doppler Waveform.
2.	**Edan Acclarix LX8 Diagnostic Ultrasound System [K180862] (Reference Device)**	The intended use and indications for use of the FloPatch FP120 are a subset of the intended use and indications for use of the Edan Acclarix LX8. The Edan Acclarix LX8 Ultrasound System device can display and automatically trace the captured Doppler spectrogram, calculate the VTI (velocity time integral) and heart rate in the CW Doppler mode.
3.	**FloPatch FP110 [K191388] (Reference Device)**	The FloPatch FP110 has the has the same intended use and indications for use as the FloPatch FP120. The method of attachment of the ultrasound probe to the human body used in the FloPatch FP120 is identical to that of the FloPatch FP110.

The subject device and the predicate has the same intended use and indications for use (Intended use and indications of use of the FloPatch FP120 are a subset of the intended use and indications for use of the Edan Acclarix LX8 Diagnostic Ultrasound System [**K180862**]).The subject device and the predicate use Continuous Wave (CW) Doppler to detect blood flow in peripheral vasculature. The subject device and the predicate can trace the Doppler flow spectrogram and can calculate metrics from the Doppler waveform. The main difference between the predicate and the subject device exists in the way the ultrasonic transducer is placed on the human body. This different method of placing the ultrasonic transducer on the body has been evaluated as part of a usability study, it has also been evaluated by the FDA as part of a previous submission for a the FloPatch FP110 [**K191388**] and it has been determined that those differences do not raise different concerns of safety or efficacy.

Hence, the FloPatch FP120 is substantially equivalent to the identified predicate device. Further the reference devices provide legally marketed devices that are intended to provide scientific and/or technical information (e.g., test methodology) to help address the safety and effectiveness of a new technological characteristic.

9. Determination of Substantial Equivalence

The FloPatch FP120 is substantially equivalent to the predicate device(s). The FloPatch FP120 has been tested to comply with relevant recognized consensus standards. The combination of testing to recognized consensus standard and performance verification testing substantiates the claim of substantial equivalnce of the FloPatch FP120.

Non-Clinical Performance Data

Non-clinical tests performed on in this premarket notification submission for a determination of substantial equivalence demonstrates compliance with the following standards:

ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD)
IEC 60601-2-37 Edition 2.1 2015 Medical Electrical Equipment - Part 2-37: Particular Requirements For The Basic Safety And Essential Performance Of Ultrasonic Medical Diagnostic And Monitoring Equipment
IEC 60601-1-2 Edition 4.0 2014-02 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
ISO 10993-1 Fourth Edition 2009-10-15 Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process [Including: Technical Corrigendum 1 (2010)]
ISO 10993-5 Third Edition 2009-06-01 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
ISO 10993-10 Third Edition 2010-08-01 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
ISO 10993-12 Fourth edition 2012-07-01 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

Summary of Non-Clinical Performance Testing

The FloPatch has been evaluated to and found compliant with recognized consensus standards for EMC, electrical, thermal & mechanical safety. Additionally, the device has been evaluated to and complies with the requirements of the recognized consensus standard for basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment. Further testing was conducted to verify performance, labelling, packaging and shelf life. The results of the performance testing and testing to recognized consensus standards demonstrate that the characteristics of the FloPatch FP120 are equivalent to the recognized predicate(s).

Biocompatibility

The patient contact part in the device is suface contacting, for intact skin, intended for a limited duration of contact (<24hrs). The patient contact part was tested to ISO 10993 for cytotoxicity, sensitization and skin irritation. The patient contact part met all the requirements identified in the standard and the FDA Guidance for biocompatibility.

10. Conclusion

The FloPatch FP120 is substantially equivalent to the identified predicate(s).