June 21, 2019

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

Re: K191388
Trade/Device Name: FloPatch (FP110)
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular blood flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: May 22, 2019
Received: May 24, 2019

Dear Mark Job:

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,

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)*

K191388

Device Name
FloPatch (FP110)

Indications for Use *(Describe)*
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 environments. The device is intended for prescription use 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5. 510 (k) Summary

510(k) Submission

510 (k) Summary

1. Submitter Information

Company Name:	Flosonics Medical (1929803 Ontario Corp.)
Company Address:	204-73 Elm Street, Sudbury Ontario, Canada P3C 1R7
Company Contact:	info@flosonicsmedical.com
Contact Person:	Joe Eibl, CEO

2. Device Identification

Trade Name:	FloPatch (FP110)
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 (FP110) is a non-invasive blood flow detection device intended to be used in a medical/hospital setting for use by medical professionals. The device uses ultrasound and the Doppler effect to evaluate the flow of blood. The device consists of signal processing box (main unit) and an ultrasonic vascular flow transducer. The device transmits ultrasonic waves from the vascular flow 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 box (main unit) which outputs the doppler signal to the device speaker.

5. Intended Use

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 environments. The device is intended for prescription use only.

6. Comparison to Predicate Device

Feature/Characteristic		FloPatch (FP110) (Subject Device)	Primary Predicate: Edan SD3 Vascular Doppler (4 MHz); (K140579)
Class/Classification/Product Code		Class II/DPW (21 CFR 870.2100 Cardiovascular blood flowmeter)	Class II/DPW (21 CFR 870.2100 Cardiovascular blood flowmeter)
Intended Use		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.	The SD3 Series Ultrasonic PocketDopplers (hereinafter called "the Doppler") are intended to be used by health care professionals including registered nurses, practical nurses, midwives, ultrasound technicians, and physician assistants, by prescription from licensed physicians in hospitals, clinics and private offices. The 4 MHz, 5 MHz and/or 8 MHz waterproof vascular probes are indicated for the detection of blood flow in veins and arteries for assisting in the detection of peripheral vascular disease.
Intended Users		Medical professionals such as Physicians and Nurses	Health care professionals including registered nurses, practical nurses, midwives, ultrasound technicians, and physician assistants, by prescription from licensed physicians
Use Environment		Hospitals and professional enviroments such as clinics and doctor's offices.	Hospitals, Clinics and Private offices
Patient Population		Adults, ages 18 years and older	Not Available
Intended for Prescription Use		Yes	Yes
Installation and Use		Body Worn	Hand Held
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.
Center Frequency		4 MHz	4 MHz
Global Maximum Outputs/Worst Case Setting	Max $I_{SPTA.3}$ (mW/cm^2)	21.47	18.83
	Min $I_{SPTA.3}$ (mW/cm^2)	8.23	14.85
	Max MI	0.01	0.01

Feature/Characteristic	FloPatch (FP110) (Subject Device)	Primary Predicate: Edan SD3 Vascular Doppler (4 MHz); (K140579)
Min MI	0.01	0.01
Modes of Operation	One mode, continuous	One mode, continuous
Reusable	No, single use for a single patient.	Yes, with cleaning.
Dimensions	135 mm x 108mm x 43.3 mm	168mm × 67 mm × 31 mm
Weight	<450 gms (including battery)	<350 gms (including battery)
The degree of protection against harmful ingress of liquid	IPX1 for vascular flow transducer. IPX0 for enclosure	IPX8 for transducer. IP rating for the device enclosure unknown or assumed to be IPX0 based on IEC 60601-1
Type of Power Source	Internal (AA Batteries)	Internal (AA Batteries)
Battery Operating Voltage	1.5V (single AA cell) 4.5V for battery (3 AA Cells)	1.5V (single AA cell)
Battery Chemistry	Alkaline	Alkaline Lithium
The degree of protection against electric shock	Type B	Type B
Buttons	One Power Button	One Power Button
Volume Slider	Absent	Present
Status LED	One, power and battery Indicator	One, power and battery Indicator
Calibration Required	No	No
Maintenance	Single Use Transducer	Reusable Transducer
Contact Classification	Limited Contact Duration (<24 hrs), Intact Skin, Surface Device	Not Available
Electrical Safety	ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012	IEC 60601-1:2005
EMC	IEC 60601-1-2:2014	IEC 60601-1-2:2007
Ultrasound Basic Safety and Essential Performance	IEC 60601-2-37:2015	IEC 60601-2-37:2007
Ultrasound Acoustic Output	IEC 62127-1	Not Available
Biocompatibility	ISO 10993-1	ISO 10993-1
Software Life Cycle Process	IEC 62304:2006	IEC 62304:2006

7. Determination of Substantial Equivalence

The FloPatch FP110 is substantially equivalent to the predicate device. The FloPatch FP110 has been tested to comply with relevant recognized consensus standards. The combination of testing to recongised consensus standard and performance verification testing substantiates the claim of substantial equivalnce of the FloPatch FP110.

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
IEC 62127-1 Edition 1.1 2013-02 Ultrasonics -- Hydrophones -- Part 1: Measurement And Characterization Of Medical Ultrasonic Fields Up To 40 MHz
IEC 61161:2013 Ultrasonics - Power measurement - Radiation force balances and performance requirements
IEC 62359 Edition 2.1 2017-09 CONSOLIDATED VERSION Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields

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, performance testing to compare the performance of the device to predicate was conducted besides verification of performance,packaging and labelling. The results of the performance testing and testing to recognized consensus standards demonstrate that the characteristics of the FloPatch FP110 are equivalent to the recognized predicate interms of acoustic output and performance.

8. 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.

9. Conclusion

The FloPatch FP110 is substantially equivalent to the identified predicate.