December 13, 2024

Laminar Digital Health, Inc.
% Pierre Bounaud
Principal Consultant
Rqm+
2790 Mosside Blvd, Suite 800
Monroeville, Pennsylvania 15146

Re: K242487
Trade/Device Name: Laminar P1
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: November 12, 2024
Received: November 12, 2024

Dear Pierre Bounaud:

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.

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.

Submission Number *(if known)*

K242487

Device Name

Laminar P1

Indications for Use *(Describe)*

The Laminar P1 device is a wearable and disposable, ultrasound-based (4.5 MHz, continuous-wave) patch sensor designed to detect blood flow in peripheral vessels and assist in the detection of peripheral vascular disease. The Laminar P1 device is intended to be used by medical professionals, such as physicians and nurses, in hospitals, clinics and private offices and healthcare facilities. It is to be used on adults, ages 18 years and older.

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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"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."

510(k) SUMMARY

DATE PREPARED
December 11, 2024

MANUFACTURER AND 510(k) OWNER
Laminar Digital Health, Inc.
440 N Wolfe Road, Sunnyvale, CA 94085, USA
Telephone: +1 (408) 732-9000
Official Contact: Jess Lee, CEO

REPRESENTATIVE/CONSULTANT
Pierre Bounaud, Ph.D.
Allison Komiyama, Ph.D., RAC
RQM+
Telephone: +1 (412) 816-8139
Email: pbounaud@rqmplus.com, akomiyama@rqmplus.com

DEVICE INFORMATION

Proprietary Name/Trade Name:	Laminar P1
Common Name:	Ultrasound Sensor Patch
Regulation Number:	21 CFR 870.2100
Class:	II
Product Code:	DPW
Premarket Review:	OHT2/Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices (DHT2A)
Review Panel:	Cardiovascular

PREDICATE DEVICE IDENTIFICATION
The Laminar P1 is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K191388	FloPatch (FP110) / Flosonics Medical	✓

The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION
The Laminar P1 is an ultrasound-based battery-powered sensor patch designed to detect blood flow in veins and arteries to assist in the detection of peripheral vascular disease. The Laminar P1 consists of a single use sensor patch, a single use patch frame, and a reusable processing unit. The sensor patch is designed to have the same performance characteristics as traditional ultrasound transducer probes (4.5 MHz frequency) but in a patch form factor that is easy to place on the patient's body for a given time period. The patch frame is a sticky frame that aids in the positioning and alignment of the processing unit. The processing unit controls the piezoelectric transducers in the sensor patch and has a built-in speaker with volume-control, like the

traditional handheld Doppler devices, and operates in the Doppler continuous-wave mode (4.5 MHz frequency). The Processing Unit is battery-operated.

INDICATIONS FOR USE

The Laminar P1 device is a wearable and disposable, ultrasound-based (4.5 MHz, continuous-wave) patch sensor designed to detect blood flow in peripheral vessels and assist in the detection of peripheral vascular disease.

The Laminar P1 device is intended to be used by medical professionals, such as physicians and nurses, in hospitals, clinics and private offices and healthcare facilities. It is to be used on patients, ages 18 years and older.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Laminar Digital Health, Inc. believes that the Laminar P1 is substantially equivalent to the predicate device based on the information summarized here:

Both devices have the same intended use, i.e., to detect blood flow in peripheral vessels for assisting in the detection of peripheral vascular disease. Both devices are intended for the same patient population and the same use environments.

The subject device shares similar technological characteristics with the predicate device. Both devices use the Doppler effect to detect blood flow in peripheral vasculature via piezoelectric transducers and one continuous wave mode.

Main differences in technological characteristics include:

- Smaller form factor – The subject device is smaller and lighter than the predicate. This difference has undergone testing to ensure the subject device is as safe and effective as the predicate.
- Transducer frequency – The subject device operates at 4.5 MHz while the predicate device features a flat face probe at 4 MHz. This does not raise different questions of safety or effectiveness.
- Global maximum outputs – Global maximum outputs for the subject device are higher than the predicate. This difference has undergone testing to ensure the subject device is as safe and effective as the predicate.
- Volume level and receiver options – The subject device offers a choice of volume levels and three ultrasound receiver options (shallow, medium, and deep) to boost signal quality. The user can cycle between the three options to pick the best audio sound quality and amplitude. This does not raise different questions of safety or effectiveness.

These differences have undergone testing to ensure the subject device is as safe and effective as the predicate device.

	Subject Device Laminar P1	***Predicate Device*** FloPatch (FP110) K191388
Indications for Use	The Laminar P1 device is a wearable and disposable, ultrasound-based (4.5 MHz, continuous-wave) patch sensor designed to detect blood flow in peripheral vessels and assist in the detection of peripheral vascular disease. The Laminar P1 device is intended to be used by medical professionals, such as physicians and nurses, in hospitals, clinics and private offices and healthcare facilities. It is to be used on patients, ages 18 years and older.	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.
Product Code	DPW	DPW
Use Environment	Healthcare settings	Healthcare settings
Patient Population	18 years and older	18 years and older
Installation and Use	Body Worn	Body Worn
Applications	Peripheral vascular	Peripheral vascular
Device Description	The Laminar P1 is an ultrasound-based battery-powered sensor patch designed to detect blood flow in veins and arteries to assist in the detection of peripheral vascular disease. The sensor patch is designed to have the same performance characteristics as traditional ultrasound transducer probes (4.5 MHz frequency) but in a patch form factor that is easy to place on the patient's body for a given time period.	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.
Device Components	• Processing Unit • Sensor Patch with Patch Frame • Power Cable	• Main Unit (signal processing box) • Ultrasonic transducer
Dimensions (Length x Width x Height)	52 x 38 x 22 mm	135 x 108 x 43.3 mm
Weight	44 grams	<450 grams
Principle of Operation	Doppler effect to detect blood flow in peripheral vasculature	Doppler effect to detect blood flow in peripheral vasculature
Modes of Operation	One mode, continuous	One mode, continuous
Transducers	4.5 MHz probe	4 MHz probe

		Subject Device Laminar P1	***Predicate Device*** FloPatch (FP110) K191388
Global Maximum Outputs	**$I_{SPTA,\alpha}$ (mW/cm^2)**	204.89	21.47
	MI	0.0537	0.01
Operational Modes		• Volume levels (silent, low, medium, high) • Receiver options for signal strength (shallow, medium, deep)	No Volume slider
Audio Bandwidth		150 Hz – 2 KHz	N/A
Audio Power		0.8 W	N/A
Power Source		Rechargeable 3.7V lithium-polymer battery	Internal AA alkaline batteries
Maintenance		• Reusable processing unit • Single use sensor patch and patch frame	Single use transducer

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed to demonstrate substantial equivalence based on current industry and FDA recognized standards:

- Biocompatibility per ISO 10993-1 and FDA's guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*
- Software per IEC 62304 and FDA's guidance *Content of Premarket Submissions for Device Software Functions*
- Electrical and EMC safety per IEC 60601-1 and IEC 60601-1-2
- Acoustic output levels per IEC 60601-2-37 and IEC 62359
- Bench performance testing (functional testing, audio performance testing, mechanical testing)

The results of these tests indicate that the Laminar P1 is substantially equivalent to the predicate device.

SUMMARY OF CLINICAL TESTING

No clinical testing was provided to support the demonstration of substantial equivalence.

CONCLUSION

Based on the testing performed, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device. The indications for use, technological characteristics, and performance characteristics for the proposed Laminar P1 are assessed to be substantially equivalent to the predicate device.