July 26, 2021

Laser Associated Sciences, Inc.
Sean White
President and CEO
5171 California Ave., Suite 150
Irvine, California 92617

Re: K192966
Trade/Device Name: FlowMet
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular blood flowmeter
Regulatory Class: Class II
Product Code: DPW

Dear Sean White:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated January 10, 2019. Specifically, FDA is updating this SE Letter to correct the SE letter date to January 10, 2020 as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact LCDR Stephen Browning, OHT2: Office of Cardiovascular Devices, with phone number of 240-402-5241, and email address of Stephen.Browning@fda.hhs.gov.

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

January 10, 2019

Laser Associated Sciences, Inc.
Sean White
President and CEO
5171 California Ave., Suite 150
Irvine, California 92617

Re: K192966
Trade/Device Name: FlowMet
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: December 10, 2019
Received: December 11, 2019

Dear Sean White:

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 C. Browning -S5

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)*
K192966

Device Name
FlowMet

Indications for Use *(Describe)*
The FlowMet is a non-invasive probe that is affixed to the fingers or toes and intended to quantify tissue blood flow rate.

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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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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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

Submitter's Name and Address

Laser Associated Sciences, Inc.
5171 California Ave.
Suite 150
Irvine, CA 92617
Tel: (949) 662-8892
Contact Person for this submission: Sean White

Date of Summary

The summary was prepared 1 of September 2019 and revised on 6 of December 2019.

Device Information

Trade name:	FlowMet™
Model No:	FlowMet™
Type of product:	Finished product
Panel:	Cardiovascular
Common Name:	Peripheral Blood Flow Monitor
Classification Name:	Cardiovascular blood flow meter
Indications for Use:	The FlowMet™ is a non-invasive probe that is affixed to the fingers or toes and intended to quantify tissue blood flow rate.
Class:	II
Classification Regulation:	870.2100
Product Code:	DPW

Predicate Device Information

Trade name:	FlowMet-R™
Model No:	FlowMet-R™
Type of product:	Finished product
Panel:	Cardiovascular
Common Name:	Peripheral Blood Flow Monitor
Classification Name:	Cardiovascular blood flow meter
Indications for Use:	The FlowMet-R™ is a non-invasive probe that is affixed to the fingers or toes and intended to quantify tissue blood flow rate.

Class:	II
Classification Regulation:	870.2100
Product Code:	DPW
510(k) No.	K182494

Device Description

Intended Use / Indications for Use
The FlowMet™ is a non-invasive probe that is affixed to the fingers or toes and intended to quantify tissue blood flow rate.

Summary of technological characteristics of Device and Predicate Device
Both the FlowMet-R™ and the FlowMet™ use the same fundamental scientific technology for the assessment of peripheral tissue blood flow: Laser Speckle Imaging. Both devices also share the same indications for use. The predicate device, the FlowMet-R™, affixes to the digit via a spring-loaded clip-on mechanism; whereas the FlowMet™ device affixes to the digit using medical tape. Additionally, the FlowMet-R™ can be cleaned and re-used, whereas the FlowMet™ is a single use device.

Comparison to the predicate device K182494, FlowMet-R™

Laser safety
The FlowMet-R™ and FlowMet™ are classified as a Class I laser product according to IEC 60825-1:2014, and employ identical laser diodes as the energy source.

Measurement Site
The FlowMet-R™ and FlowMet™ use the same measurement site: finger or toe.

Sterility
The FlowMet-R™ and FlowMet™ are both supplied non-sterile.

Affixed sensor
The FlowMet™ probe is affixed to the digit (finger or toe) using a medical tape that is wrapped around the digit, whereas the FlowMet-R™ uses a clip-on probe designed to be affixed to the fingers or toes via pressure/friction.

Performance Data
FlowMet-R™ and FlowMet™ performance was verified under known flow rate conditions using the same performance test that established substantial equivalence between the FlowMet-R™ and its predicate. The FlowMet-R™ and FlowMet™ measured the same sample concurrently: a tissue analog containing fluid pumped through at controlled volumetric flow rates. The flow rates were varied from 2-20ml/min, which includes and exceeds the normal human physiological range. At each flow rate, data was collected concurrently from both devices. Both devices exhibited high linearity (FlowMet-R™ $R^2 > 0.99$, FlowMet™ $R^2 > 0.99$) between data output and flow rate, and both devices exhibited a coefficient of variation between trials of less than 5%. Additionally, the correlation coefficient of measured flow rate between the devices was $R>0.999$.

Clinical Data
No clinical testing was performed.

A description of the technological characteristics of the FlowMet-R™ system and FlowMet™ system is provided below.

Device	FlowMet-R™, K182494	FlowMet™, Pending
Indications for Use	A non-invasive probe that is affixed to the fingers or toes and intended to quantify tissue blood flow rate.	**Same as predicate.**
Intended Use	A non-invasive probe that is affixed to the fingers or toes and intended to quantify tissue blood flow rate.	**Same as predicate.**
Fundamental Scientific Technology	Laser speckle imaging, wherein changes in the contrast of a laser speckle pattern are caused by the movement of blood within tissue, which is captured using a camera sensor.	**Same as predicate.**
Type of Use	Reusable	Single-use
Light Source	Infra-red Laser Light, 785 nm, Class 1 per IEC 60825-1:2014	**Same as predicate**
Detector	Digital CMOS camera for laser speckle imaging.	**Same as predicate**
Biocompatibility	Material intended to contact skin (silicone rubber) tested for biocompatibility per ISO-10993.	Materials intended to contact skin (silicone and acrylic adhesives) tested for biocompatibility per ISO-10993.
Physical Structure	Light source (laser diode) and detector (CMOS camera) secured in clip-on ABS/PC housing. Light source and detector are oriented to allow transillumination of digit.	Light source (laser diode) and detector (CMOS camera) secured in ABS/PC housings which are affixed to the digit using medical tape. Light source and detector are oriented to allow transillumination of digit.

Summary
The FlowMet™ and the FlowMet-R™ both use the same fundamental scientific technology for the measurement of blood flow rate and both devices share the same indications for use. The primary change from the predicate to the FlowMet™ is the transition from a spring-loaded clip to medical tape for attachment of the device to the digit. This change results in the FlowMet™ probe becoming single use.