February 26, 2021

Arterial Stiffness Inc.
Nida Shoubash
Partner
1000 Westgate Drive Suite 101B
Saint Paul, Minnesota 55114

Re: K200567
Trade/Device Name: ASI Plethysmograph Analyzer Model 3.01
Regulation Number: 21 CFR 870.2780
Regulation Name: Hydraulic, Pneumatic, Or Photoelectric Plethysmographs
Regulatory Class: Class II
Product Code: JOM
Dated: February 28, 2020
Received: March 4, 2020

Dear Nida Shoubash:

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)*
K200567

Device Name
ASI Plethysmograph Analyzer Model 3.01

Indications for Use *(Describe)*
The device provides non-invasive measurement of pulse waveform and heart rate by photoelectric plethysmography.

For Professional Use only.
Not for use in individuals under the age of 18 years.

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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510(K) Summary of Safety and Effectiveness

Arterial Stiffness Inc.
Contact: Marshall Ring, CEO
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Winnipeg, Canada R3B 0P3
Phone: 204.272.2406

February 8, 2020

Contact:
US Agent: Joseph Shaw
c/o International Life Science Enterprises Inc.
1000 Westgate Drive, St Paul, MN55114
Phone: 651.208.9596
Fax: 651.641.2801
Email: jshaw@il-se.us

1. Identification of Device

- *Proprietary Trade Name:* ASI Plethysmograph Analyzer 3.01
- *Classification Name:* Class II Device, Plethysmograph, Photelectric, Product Code JOM
- *Common/Usual Name:* Photoelectric Plethysmograph

2. Equivalent legally marketed devices

- This product is similar in function to the McPulse Photoelectric Plethysmograph (AKA Meridian DPA) 510(k) No. K023238, Applicant Meridian Co. Ltd.
- Also, Novametrix Pulse Oximeter, Model 500, 510(k) K853124

3. Indications for Use (intended use):

- The device provides non-invasive measurement of pulse waveform and heart rate by photoelectric plethysmography – For professional use only. Not for use individuals under the age of 18 years.

4. Description of the device

The ASI Device is intended to be used to measure pulse waveform in the finger. The measurement oximeter is an optoelectronic sensor consisted of a light- emitting diode (infrared LED) and a photodiode placed on opposite side as a light receiver. The ASI System incorporates an FDA approved pulse oximeter fingertip probe. The light from the LED is transmitted through the tissue at the sensor site and a photodiode in the sensor measures the transmitted light and calculating how much light is absorbed. This device converts the changes of transmitted light from a photodiode into a waveform and displays a graphic display of the pulse waveform on computer screen. As well as the optoelectronic sensor, the system utilizes a Texas Instrument designed circuit board which in turn transfers the signal to the computer. The computer contains the downloaded ASI proprietary algorithm which analysis the generated plethysmograph. The ASI System measures and analyzes the generated pulse waveforms to produce heart rate and plethysmograph of the patient's blood circulation.

5. Safety and Effectiveness, comparison to predicate device

The results of both bench testing and clinical trial data indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence chart

Feature	McPulse (Meridian DPA)	ASI Plethysmograph Analyzer 3.01
INDICATION OF USE	The device provides non-invasive measurement of pulse waveform and heart rate by photoelectric plethysmography	The device provides non-invasive measurement of pulse waveform and heart rate by photoelectric plethysmography
MODE	Noninvasive	Noninvasive
PRACTITIONER USE	For professional use only	For professional use only
DISPLAY	Digital LCD Display	Computer LCD screen
POWER SOURCE	AC (100-240Vac)	USB power source, A USB 3.0 cable supplies up to 900 milliamps of power to reading device
TYPE OF SENSOR	LED – Photodiode/finger probe	LED – FDA approved Oximeter. 510(k) 822909, Nellcor™, (Medtronic)
ANATOMICAL SITE	Finger	Finger
RECORDER OUTPUTS	Pulse Waveform Hear rate	Pulse Waveform Hear rate
HEART RATE & DISPLAY RESOLUTION	30-230 bpm	30-230 bpm
SIZE (UNIT: MM)	305x296x92.5 mm	80x160x40 mm (not including computer)
WEIGHT	Approx. 5.5 kg	Approx. 0.18 kg (Not including computer)
CONFIGURATION	Integrated unit including printer, pre-programed CPU and software program built in.	CPU and software included in separate computer and provided on disc. Operating system Windows 10

7. Non-clinical and Clinical Tests

Clinical and non-clinical tests were performed to support the determination of substantial equivalence. These tests were performed at independent CRO Prism Research at 1000 Westgate Drive, Saint Paul, Minnesota 55114. Clinical studies were conducted following regulations under Title 21 of the Code of Federal Regulations (21 CFR), Part 812- Investigational Device Exemptions, Part 50- Protection of Human Subjects and Parts 56-Institutional Review Boards. Statistical Analysis was performed by ASI Staff.

8. Conclusion

After analysis the bench responses and considerations of electrical safety combined with clinical trial data it is the conclusion of Arterial Stiffness Inc., that the ASI Plethysmograph Analyzer has few technological differences and those that do exist represent little or no significance thus rendering it substantially equivalent to the predicate device.