**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 5, 2015

Semler Scientific, Inc.
Bob McRae
Chief Operating Officer
2330 NW Everett Street
Portland, Oregon 97210

Re: K143094
Trade/Device Name: QuantaFlo
Regulation Number: 21 CFR 870.2780
Regulation Name: Hydraulic, Pneumatic, or Photoelectric Plethysmographs
Regulatory Class: Class II
Product Code: JOM
Dated: January 23, 2015
Received: January 29, 2015

Dear Bob McRae,

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K143094

Device Name
QuantaFlo

Indications for Use *(Describe)*
QuantaFlo is intended to aid clinicians in the diagnosis and monitoring of Peripheral Arterial Disease. It provides bilateral, non-invasive physiologic studies of the upper and lower extremity arteries, using volume plethysmography of the posterior tibial and anterior tibial/dorsalis pedis arterial distributions. Additionally, QuantaFlo may be used to perform bilateral, non-invasive physiologic studies of the upper and lower extremity arteries with provocative functional maneuvers.

The device is for adult use and not for pediatric or fetal use.

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."*

# 510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

## Submitter


| | |
|---|---|
| Company Name: | Semler Scientific, Inc. |
| Address: | 2330 NW Everett St, Portland OR 97210 |
| Phone: | 877-774-4211 |
| Fax: | 800-303-7259 |
| | |
| Contact: | Bob McRae, Chief Operating Officer |
| Date of Preparation: | February 23, 2015 |


## Device

| | |
|---|---|
| Name of Device: | QuantaFlo™ |
| Common or Usual Name: | Plethysmograph |
| Classification Name: | Hydraulic, pneumatic, or photoelectric plethysmographs (21 CFR 870.2780) |
| Regulatory Class: | II |
| Product Code: | JOM |

## Predicate Device

FloChec® (K093192)

## Device Description

QuantaFlo aids clinicians in the diagnosis of vascular disease by measuring blood volume changes using volume plethysmography in the Brachial, Posterior Tibial, and Anterior Tibial/Dorsal Pedis arterial distributions. From these signals it calculates a result that is predictive of Peripheral Arterial Disease (PAD). In addition, QuantaFlo provides hard-copy waveforms as part of the report, which may be viewed on the system display, printed, and/or saved.

The clinician places a sensor and makes a measurement on each upper extremity and each lower extremity. The sensor includes a transducer, which detects changes in arterial blood volume. This signal is digitized and sent to a computer, which runs a specifically-designed software application. The application calculates the result via a proprietary algorithm, which is based on the features of the volume plethysmography signals from the Brachial, Anterior Tibial / Dorsalis Pedis, and Posterior Tibial arterial distributions.

# Indications for Use

QuantaFlo is intended to aid clinicians in the diagnosis and monitoring of Peripheral Arterial Disease. It provides bilateral, non-invasive physiologic studies of the upper and lower extremity arteries, using volume plethysmography of the posterior tibial and anterior tibial/dorsalis pedis arterial distributions. Additionally, QuantaFlo may be used to perform bilateral, non-invasive physiologic studies of the upper and lower extremity arteries with provocative functional maneuvers.

The device is for adult use and not for pediatric or fetal use.

# Technological Comparison to Predicates

QuantaFlo uses the same technology as the predicate device. That is, it uses Volume Plethysmography of the same arterial distributions, digitizes that signal, and processes those signals via a specially-designed algorithm to calculate a result. Each device uses use a transducer, which makes non-invasive measurements with brief-contact sensors. QuantaFlo, like the predicate is a software-based device, which runs on a computer. The QuantaFlo sensor is the same as the predicate, but includes a clamshell to house the electronics.

# Performance Data

The following performance data were provided in support of the substantial equivalence determination.

## Biocompatibility Testing

The biocompatibility evaluation for the QuantaFlo device was conducted in accordance with ISO-10993. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

## Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical EMC testing was conducted on the QuantaFlo device, consisting of the PC and Sensor. The system complies with the IEC 60601-1-2 standard for EMC. Additionally, an electrical safety analysis was conducted on the QuantaFlo device. While the QuantaFlo System has Patient Applied Parts, all conductive parts are insulated by plastic material with adequate dielectric strength to withstand the 3,500VAC test potential. All electronics are powered via a SELV safe low voltage interface.

## Software Verification and Validation Testing

Software validation included application stability testing under load, USB sensor connection cycle testing, standard use-case testing, and automated use / “stress” testing. Product validation involved simulated use testing. The Level of Concern of QuantaFlo is considered a Moderate Level of Concern because it could: …lead to an erroneous

diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

## Design Verification & Product Validation Testing

Product testing was completed and met all of the acceptance criteria. Verification testing involved several tests such as: dimensional verification, signal quality measurements, temperature stability testing, accelerated life testing, tensile testing of the cable to the sensor body, and electrical EMC testing. All necessary verification and validation testing has been performed for the QuantaFlo to assure substantial equivalence to the predicate devices.

## Clinical Performance Data

The clinical performance of the QuantaFlo was assessed compared to the pressure cuff / Doppler probe ABI method, using Duplex ultrasound and/or angiography as the reference standard. Thus, using the reference diagnostic standard, the clinical accuracy of each technology was compared. Among six clinical sites, QuantaFlo was 80.2% accurate (n=333 limbs) and Doppler ABI was 79.3% accurate (328) limbs. Doppler ABI is an accepted standard for aiding in the diagnosis of PAD[1]. The submitted study demonstrates QuantaFlo's substantially equivalent accuracy in determining the presence of PAD.

## Conclusions

QuantaFlo shares many of the technological features as the predicate. Any differences either have no effect on safety or efficacy, or have been performance tested, assuring substantially equivalence. Further, clinical data has demonstrated efficacy in the detection of clinically significant flow obstruction.

[1] Rooke TW, et al, "2011 ACCF/AHA focused update of the guideline for the management of patients with peripheral artery disease (updating the 2005 guideline): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines." J Am Coll Cardiol 2011;58:2020–45.