K093192
P1/2

ADVANCED VASCULAR DYNAMICS
A Semler Technologies Company

FEB 12 2010

510(k) Summary

Herbert J. Semler
21 December 2009

Company: Advanced Vascular Dynamics
Address:
1910 NW 23rd Place
Portland, Oregon 97210
USA

Employer identification number is PIN — 9440
Contact Person: Herbert J. Semler, M.D.
Submitted device is FloChec Photoplethysmography Device.
Preparation Date: December 21, 2009.
Advanced Vascular Dynamics is a registered medical device manufacturer establishment, registration number 3035234. Small business number is SBD 107113.
Trade name is FloChec™ Photoplethysmographic Device.

Revised 510K Summary
Herbert J. Semler
December 21, 2009

Predicate Devices – Hokanson EC-6 (K9882707), Parks Medical Mini-Lab (K944495)

The FloChec Plethysmograph Device (PPG) is similar to the PPG portion of the Hokanson EC-6 but does not include a strain gauge PPG function that is included in the EC-6. The FloChec Sensor is similar to that of the Parks' Mini-Lab which used a single wave length IR emitter in the sensor. The device is not sterile. Use of the FloChec device by a medical practitioner allows visualizing of the blood flow wave forms in the extremities. In viewing the effects on the wave forms as a result of events such as direct external pressure being applied proximal to the sensor.

FloChec Photoplethysmography is intended for use to provide visualization and evaluation of the blood flow wave form in an extremity. Testing was conducted to determine if the FloChec Photoplethysmography Device provides a visual representation of the PPG wave form in the extremities. It was concluded that the FloChec device is equivalent to the predicate device.

Caution: Federal Law restricts this device to sale by or on the order of a licensed healthcare practioner.

The submitted device is expected to retain the same classification as the predicate device, Hokanson Device, model EC-6 Plethysmograph, 510(k) number K982707. This device carries the classification of Class 2, Product code JOM.

Refer to section 2.1 of this 510K for the description of the device.

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Indications for use would be unexplained pain or claudication discomfort in an extremity, based on the history and physical findings performed by a licensed physician. The device may be used to detect relative blood flow changes before, during and after applied pressure to the brachial, femoral, radial and ulnar arteries. The FloChec Device is not for diagnosis nor is it indicated for the treatment, prevention, cure or mitigation of a disease. The indications for the device are not different from those of the legally marketed device identified in the preceding paragraphs.

The device is contraindicated in subject's who do not have fingers or toes. The device has been tested in adults but not in children or the fetus.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB 12 2010

Advanced Vascular Dynamics
c/o Herbert Semler, M.D., F.A.C.C.
Official Correspondent
1910 NW 23rd Place
Portland, OR 97210

Re: K093192
Trade/Device Name: FloChec™ Photoplethysmography Device
Regulatory Number: 21 CFR 870.2780
Regulation Name: Hydraulic, pneumatic, or photoelectric plethysmographs
Regulatory Class: II (two)
Product Code: 74 JOM
Dated: December 22, 2009
Received: January 6, 2010

Dear Dr. Semler:

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.

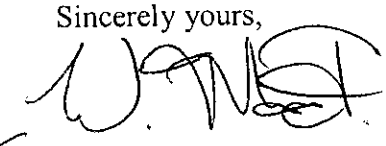
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093192

510(k) Number (if known): K093192

Device Name: FloChec™ Photo Plethysmography Device

Indications For Use:

To monitor relative blood flow changes distal to the occlusion of a brachial, radial, ulnar, or femoral artery.

From the physician history and clinical findings, the person has pain, claudication, or changes in blood flow to the extremity..

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

Rx X or OTC _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093192

(Optional Format 3-10-98)