K090286

MAR 2 3 2009

31 December 2008

510(k) Summary

Company Contact Information
Advanced Vascular Dynamics
1910 NW 23rd Place, Portland, Oregon 97210
Herbert J. Semler, President, Advanced Vascular Dynamics
Phone: (800) 525-2555
Fax: (503)223-8585

Name of Device
Trade name - PressureMate™ Compression Assist Handle
Common name – Femoral Access Compression Device
Procode/Classification name – DXC/Clamp, Vascular
Regulation Number – 870.4450

Predicate Device(s)
Compass Compression Assist Handle (K053398)
SuperComfort™ Discs (K040615)

Indication for Use
The device is indicated for use to provide hemostasis of the femoral vascular access site during and following catheterization or cannulation procedures.

Device Description
The PressureMate™ Compression Assist Handle mates with the SuperComfort™ Discs (K040615) to provide an alternative to the use of mechanical clamping systems or direct hand holding pressure to obtain hemostasis following femoral vascular catheterization procedures.

The PressureMate™ handle itself is an aluminum handle with stainless steel stem. The stem ends in a female connection which mates to the male connector located on the SuperComfort Discs. The handle can not be used without a Disc.

The PressureMate™ comes in two designs: i) symmetrical, with both ends symmetrically tapering down at each end and centrally located stem or ii) asymmetrical, with one end tapered smaller than the other end and the stem slightly off center. The handle designs, round with tapered ends, enable better fit to an operator's hand.

Use of the handle and disc by a medical practitioner avoids prolonged direct contact with bodily fluids, and alleviates bio-mechanical stress which may occur during traditional direct digital compression of the femoral artery post-cardiac catheterization.

Performance Data
The device is designed and has been tested to withstand a holding force of 35 pounds.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2009

Advanced Vascular Dynamics
c/o Mr. Matthew Semler
1910 NW 23rd Place
Portland, OR 97210

Re: K090286
PressureMate™ Manual Femoral Access Compression Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Compression Device
Regulatory Class: Class II
Product Code: DXC
Dated: January 30, 2009
Received: February 5, 2009

Dear Mr. 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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K090286

Device Name: PressureMate™ Manual Femoral Access Compression Device

Indications for Use:

This device is indicated for use to provide hemostasis of the femoral vascular access site during and following catheterization or cannulation procedures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090286