



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2007

Pulsion Medical Systems AG
c/o Dr. Jamie Sulley
President
Triangulum Consulting Services, Inc.
7220 Sparhawk Rd.
Wake Forest, NC 27587

Re: K072364
Pulsion Pulsioath ThermoDilution Catheters and Accessories
Regulation Number: 21 CFR 870.1915
Regulation Name: ThermoDilution Probe
Regulatory Class: Class II
Product Code: KRB
Dated: August 20, 2007
Received: August 22, 2007

Dear Dr. Sulley:

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.

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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 Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

Danna R. Vachner

BZ

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

Enclosure

Indications for Use

510(k) Number (if known): K072364

Device Name: Pulsion Pulsiotech Thermodilution Catheters and Accessories

Indications for Use:

The Pulsion Pulsiotech Thermodilution Catheter and Pressure Monitoring Kit with Injectate In-Line Sensor are intended for use with the Pulsion PiCCO Cardiac Output System for the measurement of cardiac output by the thermodilution method, measurement of arterial blood pressure, and for cardiac output determination by arterial pulse contour analysis. The Pulsion PiCCO Cardiac Output System with Thermodilution Catheter and Pressure Monitoring Kit with Injectate In-Line sensor is indicated in patients where cardiovascular and circulatory volume status monitoring is necessary. Such as patients in surgical, medical, cardiac, and burn specialty units as well as other specialty units where cardiovascular monitoring is desired and patients undergoing surgical interventions of such magnitude that cardiovascular monitoring is necessary.

Prescription Use (Per 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Suzanne R. Vechnes
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072364