



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - W066-G609
Silver Spring, MD 20993-0002

Pulsion Medical Systems, Inc.
c/o Dr. Jamie Sulley
US Agent
1511 Essex Road
Westbrook, CT 06498

SEP 22 2011

Re: K112448
Trade/Device Name: PulsioFlex, Model Number PC4000
Regulatory Number: 21 CFR 870.1435
Regulation Name: Single-function, Preprogrammed Diagnostic Computer
Regulatory Class: II (two)
Product Code: 74 DXG
Dated: August 19, 2011
Received: August 25, 2011

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.

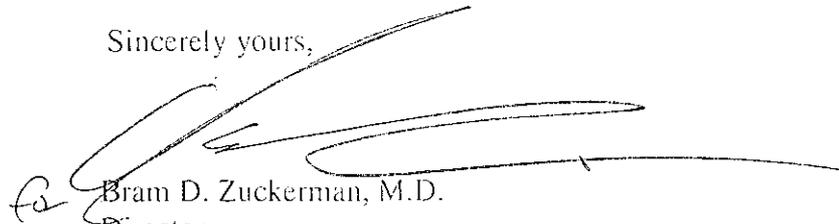
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



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

Enclosure

PULSION

Medical Systems

Appendix B

Indications for Use Statement

510(k) Number (if known):

Device Name: PulsioFlex Monitoring System with Optional CeVox™ Accessories

Indications for Use:

With the optional CeVox™ oximetry module connected to a compatible PulsioFlex oximetry probe, PulsioFlex measures oxygen saturation to assess oxygen delivery in adults.

The following tabular shows the parameters measured by the PulsioFlex monitor and its specifications:

| Label | Unit | Lower Limit | Upper Limit | Accuracy* | Remark |
|-------------------|------|-------------|-------------|-----------|-------------------|
| SO ₂ | % | 1 | 99 | +2% | Valid from 40-99% |
| SvO ₂ | % | 1 | 99 | +2% | Valid from 40-99% |
| ScvO ₂ | % | 1 | 99 | +2% | Valid from 40-99% |

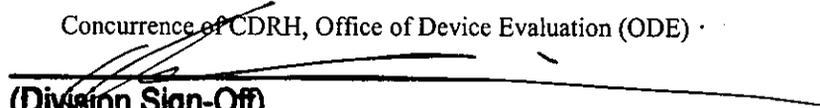
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112448

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(Posted November 13, 2003)