



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AUG 2 2012

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

Re: K122121
Trade/Device Name: PulsioFlex Monitoring System with PiCCO Module
Regulatory Number: 21 CFR 870.1435
Regulation Name: Single-function, Preprogrammed Diagnostic Computer
Regulatory Class: II (two)
Product Code: 74 DXG
Dated: July 12, 2012
Received: July 17, 2012

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.

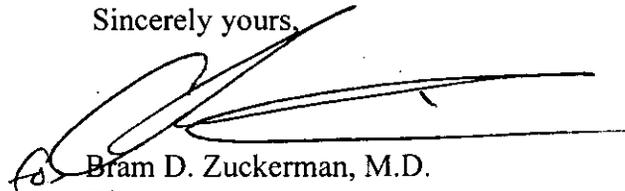
Page 2 – Dr. Jamie Sulley

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 PiCCO Module

Indications for Use:

The PULSION PulsioFlex Monitoring System with optional PiCCO Module is intended for determination and monitoring of cardiopulmonary and circulatory variables. With the optional CeVox oximetry module connected to a compatible oximetry probe, the PulsioFlex Monitoring System with PiCCO Module measures oxygen saturation to assess oxygen delivery and consumption in adults and pediatrics. Cardiac output is determined both continuously through pulse contour analysis and intermittently through thermodilution technique. In addition, the PulsioFlex Monitoring System measures heart rate, systolic, and diastolic and derives mean arterial and central venous pressure. Analysis of thermodilution curve in terms of mean transit time and downslope time is used for the determination of intravascular and extravascular fluid volumes. If a patient's weight and height are entered, the PulsioFlex monitor presents the derived parameters indexed to body surface area.

The following tabular shows the parameters measured by the PulsioFlex Monitoring System with PiCCO Module and CeVox Accessories and their specifications:

Label	Unit	Lower Limit	Upper Limit	Accuracy*	Remark
CO	l/min	0.25	25	Coefficient of variation $\leq 2\%$	Valid over a full range
GEDV	ml	40	4800	Coefficient of variation $\leq 3\%$	Valid over a full range
EVLW	ml	10	5000	Coefficient of variation $\leq 6\%$	Valid over a full range
PCCO	l/min	0.25	25	Coefficient of variation $\leq 2\%$	Valid over a full range
SV	ml	1	250	Coefficient of variation $\leq 2\%$	Valid over a full range
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%

* Statistical evaluation based on random examination of actual production output

Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

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

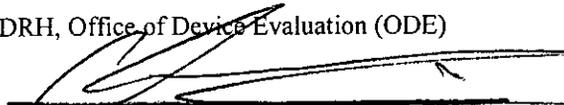
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Posted November 13, 2003)

12 July, 2012


(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number R122121

Page B-1