K991886

MAY 11 2000

10.0 510(k) Summary.

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §.807.92.

1. The submitter of this premarket notification is:

Ulf Borg
PULSION US
8911 Sedgley Drive
Wilmington NC 28412
Tel.: (910) 452-7386
Fax.: (910) 793-9479

This summary was prepared on May 13, 1999.

2. The name of this device is the PULSION Pulsiocath Thermodilution Catheter with J-Guidewire and needle , and a monitoring kit including an in-line injectate sensor used as accessories to the Pulsion Continuous Pulse Contour Cardiac Output System (PiCCO). The common names are thermodilution catheter, J-Guidewire and needle pressure monitoring kit/disposable pressure transducer, and in-line injectate sensor. Classification names are as follows:

REGULATION NUMBER	CLASSIFICATION NAME
870.1240	Flow-directed catheter
870.1330	Catheter guidewire and accesssories
870.2850	Extravascular blood pressure transducer
870.1915	Thermodilution probe

3. The Pulsion Pulsiocath Thermodilution Catheter and introducer accessories are substantially equivalent to the Baxter Swan-Ganz® VIP™ Thermodilution Catheter marketed pursuant to K810124, and the Arrow International Radial (Femoral) Artery Catheterization Set marketed under K810675. The Pulsion in-line injectate sensor is substantially equivalent to that marketed by Spectramed under K892941. The Pulsion Pressure Monitoring Kit and Disposable Pressure Transducer are substantially equivalent to those sold by Utah Medical pursuant to K842352 and K841788, respectively.

4. When coupled with the Pulsion Continuous Pulse Contour Cardiac Output System (PiCCO), the above device accessories, in connection with a central venous catheter, operate to measure and display cardiac output parameters.

5. The device has the same intended use as the legally marketed predicate devices.

6. The technological characteristics are the same or similar to those found with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2000

Mr. Ulf Borg
Pulsion Medical Systems, Inc.
8911 Sedgley Drive
Wilmington, NC 28412

Re: K991886
Trade Name: Pulsion Pulsiocath, Pulsion PCCO Monitoring Kit, Pulsion I
Regulatory Class: II (two)
Product Code: 74 KRB
Dated: May 3, 2000
Received: May 4, 2000

Dear Mr. Borg:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and Radiological
Health

Enclosure

510(k) Number (if known): _____

Device Name: PULSION Pulsiocath Thermodilution Catheter, with Pressure Monitoring Kit and Injectate In-Line Sensor

Indications for Use:

The PULSION Pulsiocath 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Brian E. Hanrahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K991886

Prescription Use X **OR** **Over-The-Counter Use** _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)