K062576

SEP 29 2006

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5 E-PSM(P) Module (consisting of E-PSM, E-PSMP and E-INTPSM Modules) and accessories

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

August 22, 2006

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5 E-PSM(P) Module (consisting of E-PSM, E-PSMP and E-INTPSM Modules) and accessories

COMMON NAME:

Multi-parameter Hemodynamic Module

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

Product Code	Classification Name	CFR Section
MHX	Arrhythmia detector & alarm	870.1025
MLD	Monitor ST-segment & alarm	870.1025
DQA	Oximeter	870.2700
DPZ	Ear Oximeter	870.2710
DRT	Cardiac Monitor (including cardiotachometer and rate alarm)	870.2300
DPS	Electrocardiograph	870.2340
DXN	Non-invasive blood pressure measurement system	870.1130
DSK	Blood pressure computer	870.1110
DRQ	Transducer signal amplifier and conditioner	870.2060
FLL	Clinical Electronic Thermometer	880.2910

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda E-PSM Module (consisting of E-PSM, E-PSMP and E-INTPSM modules) and accessories is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda E-PSM module (consisting E-PSM and E-PSMP Modules) and accessories (K043551).

DEVICE DESCRIPTION as required by 807.92(a)(4)

E-PSMP is a hemodynamic plug-in parameter module including the NIBP measurement, 12-lead ECG with the Impedance Respiration measurement, SpO2 with the plethysmographic waveform, two invasive pressure measurements (P1 and P2) and two temperature measurements (T1 and T2). E-PSMP is a hemodynamic measuring module for a modular monitoring system. This module can be used directly in the S/5 FM modular monitor and in other monitors using the new F-CU5P frame. With the new mounting accessories for the PSM module, E-PSM(P) plug-in parameter module can be removed from the FM monitor frame or S/5 F-CU5P frame and used near the patient on an IV-pole or anesthesia machine. Via the new E-INTPSM module and the new mounting accessories for the PSM, the E-PSM(P) plug-in parameter module can be attached directly to a monitor using the S/5 F-CU8 frame or with Compact Monitor frames or used near the patient on an IV-pole or anesthesia machine. S/5 F-CU8 frames or Compact Monitor frames have to be equipped with software license L-xxx04 or later. The monitors display waveforms and measurement readings, and handle the trending and alarm management. The ECG (e.g. heart beat and arrhythmia detection) and the Impedance Respiration algorithms are in the monitor software. The modules measure signals and send them to the monitor. The NIBP, SpO2, Temperature and Invasive Pressure algorithms are in the module. There are two available options of the module: E-PSMP with invasive pressures P1 and P2 and E-PSM without P1 and P2. There are three parameter circuit boards inside the E-PSMP module for processing the measurement signals. Each processing board has a microcontroller with software. The new E-INTPSM module and the new mounting accessories are mechanical and electrical interfacing between the E-PSM(P) module and S/5 F-CU8 or Compact monitor. The E-INTPSM module and the new mounting accessories include only connections for the power supply and module bus data communication. There are no microcontrollers or software in the module or mounting accessories.

INTENDED USE as required by 807.92(a)(5)

Intended Use:
The Datex-Ohmeda S/5 PSM module (consisting of E-PSM, E-PSMP and E-INTPSM Modules) and accessories is intended for monitoring hemodynamic parameters of hospitalized patients.

Indications for use:
The Datex-Ohmeda S/5 PSM module (consisting of E-PSM, E-PSMP and E-INTPSM Modules) and accessories are indicated for monitoring of hemodynamic parameters of all hospital patients. The hemodynamic parameters of the module comprise ECG (including ST-segment and arrhythmia), Impedance respiration, NIBP, Temperature, SpO2 (including monitoring during conditions of clinical patient motion), and invasive blood pressure.
Impedance Respiration measurement is indicated for patients ages 3 and up.
The NIBP measurement is indicated for patients who weigh 5kg (11 lbs.) and up.
The device is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda E-PSM Module (consisting of E-PSM, E-PSMP and E-INTPSM modules) and accessories is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda E-PSM module (consisting E-PSM and E-PSMP Modules) and accessories (K043551).
The E-PSMP module (consisting E-PSM, E-PSMP and E-INTPSM Modules) and accessories have the following similarities compared to the predicate E-PSMP (K043551):

- same intended use and indications for use (only difference is to add E-INTPSM to the name)
- identical fundamental scientific technology
- use the same operating principle
- the Customer and parameter specifications are the same except the Venous stasis values of the NIBP measurement
- have the same safety and effectiveness
- have the same user interface at the monitor and alarms
- are manufactured using the same processes

The main differences between the new E-PSMP and the predicate E-PSMP (K043551) is primarily due to fact that the new E-PSM module has the following changes:

- added a new interface module, E-INTPSM, on the intended use and indications for use
- with E-INTPSM the E-PSM(P) module can now used with S/5 F-CU8 monitor frame and Compact monitor
- added new mounting accessories on the accessory list of the PSM module
- added three reusable temperature probes and twelve disposable temperature probes
- added an invasive pressure sensor on the accessory list of the PSM module
- added new temperature and invasive pressure Care cables in the E-PSM(P) module accessory list
- changed core material of the NIBP choke that is used in the power supply circuit of the NIBP measurement board
- modified the software of the NIBP board to improve the Venous Stasis pressure used

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda S/5 PSM module (consisting of E-PSM, E-PSMP and E-INTPSM Modules) and accessories has been assessed against the standards below. The device has been thoroughly tested through validation and verification of specifications.

- FDA regulation 21 CFR 898.12
- IEC 60601-1:1988 + Amendments: A1:1991, ,A2:1995,
- IEC 60601-1-2:2001
- IEC 60601-1-4:1996 + A1 1999
- ANSI/AAMI ES1 (1993)
- CAN/CSA C22.2 No. 601-1-M90 + S1 (1994)+Amdt2:1998
- IEC 60601-2-27 (1994)
- IEC 60601-2-30 (1999)
- IEC 60601-2-34 (2000)
- IEC 60601-2-49:2001
- EN 12470-4:2000
- ISO 9919 (1994) / EN 865:1997
- UL 2601-1 : 1997

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the The Datex-Ohmeda S/5 PSM module (consisting of E-PSM, E-PSMP and E-INTPSM Modules) and accessories compared to the legally marketed (predicate) Datex-Ohmeda E-PSM module (consisting E-PSM and E-PSMP Modules) and accessories (K043551).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2006

GE Healthcare
c/o Mr. Joel C. Kent
Manager, Quality and Regulatory Affairs
86 Pilgrim Road
Needham, MA 02492

Re: K062576
Trade Name: Datex-Ohmeda S/5 E-PSM(P) Module and accessories
Regulation Number: 21 CFR 870.1025
Regulation Name: Physiological Patient Monitor (With Arrhythmia Detection or Alarm)
Regulatory Class: Class II (two)
Product Code: MHX, MLD, DSK, DRQ, DQA, DPZ, DRT, DPS, DXN, FLL
Dated: August 28, 2006
Received: August 31, 2006

Dear Mr. Kent:

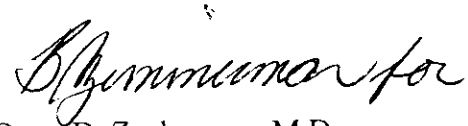
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 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,



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

Enclosure

Indications for Use

510(k) Number (if known): K062576

Device Name: Datex-Ohmeda S/5 PSM Module, (consisting of E-PSM, E-PSMP and E-INTPSM Modules) and accessories

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Impedance Respiration measurement is indicated for patients ages 3 and up.

The NIBP measurement is indicated for patients who weigh 5kg (11 lbs.) and up.

The device is indicated for use by qualified medical personnel only.

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 K062576