FEB 3 2006

K051217

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda PRESTN Module (Model family E-PRESTN, including E-PRESTN, E-RESTN,E-PRETN, E-PP,and E-PT/E-P) 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:

May 1, 2005

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

TRADE NAME:

Datex-Ohmeda PRESTN Module (Model family E-PRESTN, including E-PRESTN, E-RESTN, E-PRETN, E-PP and E-PT/E-P) and accessories.

COMMON NAME:

Multiparameter Hemodynamic Module (E-PRESTN, E-RESTN,E-PRETN)
Invasive Pressure Measurement Module (E-PP, E-P)
Invasive Pressure Temp Hemodynamic Module (E-PT)

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

Product Code	Classification Name	CFR Section
MHX	Monitor,Physiological,Patient (With Arrhythmia Detection or Alarm)	870.1025
MLD	Monitor, ST segment with 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
FLL	Clinical Electronic Thermometer	880.2910
DSK	Blood pressure computer	870.1110
DRQ	Transducer signal amplifier and conditioner	870.2060

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

The Datex-Ohmeda S/5™ E-PRESTN Module family is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-PRESTN..01 Module (K041772).).

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

The Datex-Ohmeda E-PRESTN module family and accessories is a hemodynamic multiparameter module which is able to measure ECG, two Invasive blood pressures, SpO2, two Temperatures, Non-invasive blood pressure and Impedance Respiration.
The Datex-Ohmeda E-PRESTN module can be used with the following Datex-Ohmeda modular monitors.
S/5 Anesthesia Monitor(AM) with main software L-ANE05(A)..00 or newer version
S/5 Compact Anesthesia Monitor (CAM), with main software L-CANE05(A) or newer version
S/5 Critical Care Monitor (CCM) with main software L-ICU05(A) or newer version
S/5 Compact Critical Care Monitor (CCCM), with main software L-CICU05(A) or newer version

There are 6 different model variants of the module:
E-PRESTN: (includes all possible parameters) NIBP, ECG, SpO2, 2*T, 2*inv. press.,Resp
E-RESTN: (does not include invasive pressures) NIBP, ECG, SpO2, 2*T, Resp
E-PRETN: (does not include SpO2) NIBP, ECG, 2*T, 2*inv. press.,Resp.
E-PP: Two invasive pressure measurement channels
E-PT: One invasive pressure measurement channel, dual temperature measurement channel
E-P: One invasive pressure measurement channel
The letters in the module name stand for:
P= Invasive Pressure
R= Impedance Respiration
E= 12-Lead ECG
S= Pulse Oximetry
T= Temperature
N=NIBP, Non-Invasive Blood Pressure
In the remainder of this document," E-PRESTN module family" is used to denote all six modules, "E-PRESTN" is used as a collective name for the double-width E-PRESTN, E RESTN, and E-PRETN modules, and the respecitve module names "E-PP", "E-PT" or "E-P" (or "E-PT/E-P") are used for the single-width modules.

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

Intended use:
The Datex-Ohmeda PRESTN module, model family E-PRESTN is intended to be used with Datex-Ohmeda modular monitors for monitoring hemodynamic parameters of hospitalized patients.
Indications for use:
The Datex-Ohmeda E-PRESTN module family (including E-PRESTN, E-RESTN, E-PRETN, E-PP, E-PT,a nd E-P modules) and accessories is 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 patient's ages 3 and up.
The NIBP measurement is indicated for patients who weigh 5kg (11 lb.) 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 S/5™ E-PRESTN Module family is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-PRESTN..01 Module (K041772).).
The E-PRESTN module has the following similarities compared to the predicate M-PRESTN..01 (K041772):

- identical intended use and indications for use
- identical fundamental scientific technology
- use the same operating principle
- identical ECG connector
- have the same safety and effectiveness
- the Customer and parameter specifications are basically the same (four minor modifications)
- have the same user interface at the monitor and alarms
- are manufactured using the same processes

The main differences between the new E-PRESTN and the predicate M-PRESTN..01 (K041772) is primarily due to the fact that the new E-PRESTN module has the following changes:

- New color, shape, and size and thus differing mechanics
- The front panel and labeling have changed
- New GE-type NIBP, invBP, Temperature and SpO2 module connectors
- Dynamic module addressing in the module-to-monitor communication
- Minor enhancements to module software
- Minor modifications to the electronic measurement boards
- The arrhythmia and ST detection and analysis algorithm in the monitor software supporting the E-PRESTN modules have changed. The functionality is identical, the same arrhythmias are detected and alarms are initiated for them in a identical manner.
- The single-width hemodynamic pressure and temperature modules E-PP, E-PT, and E-P have been added to the E-PRESTN Module family.

Based on the analysis and other documentation included in this 510(k) notification and attachments it is evident that the main features and indications for use of Datex-Ohmeda E-

PRESTN Module family are substantially equivalent to the predicate Datex-Ohmeda M-PRESTN..01 Module (K041772).

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

Datex-Ohmeda PRESTN Module (Model family E-PRESTN, including E-PRESTN, E-RESTN, E-PRETN, E-PP and E-PT/E-P) and accessories have 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 Datex-Ohmeda PRESTN Module (Model family E-PRESTN, including E-PRESTN, E-RESTN, E-PRETN, E-PP and E-PT/E-P) and accessories as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2006

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

Re: K051217
Trade Name: Datex-Ohmeda S/5 E-PRESTN Module Family, including E-PRESTN, E-RESTN, E-PRETN, E-PP, and E-PT/E modules
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarm)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: January 06, 2006
Received: January 06, 2006

Dear Mr. Kent,

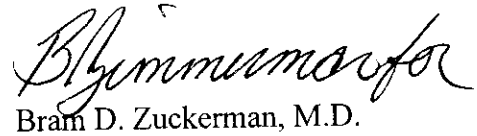
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 276-0210. 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 (301) 443-6597 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): K051217

Device Name: **Datex-Ohmeda PRESTN Module (Model family E-PRESTN, including E-PRESTN, E-RESTN,E-PRETN, E-PP and E-PT/E-P) and accessories.**

Indications for Use:

The Datex-Ohmeda E-PRESTN module family (including E-PRESTN, E-RESTN, E-PRETN, E-PP, E-PT, and E-P modules) and accessories is 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 lb.) 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 K051217