K052976

JAN 13 2006

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5™ Cardiac Output module , E-COP 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:

October 19, 2005

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

TRADE NAME:

Datex-Ohmeda S/5™ Cardiac Output module , E-COP and accessories

COMMON NAME:

Cardiac Output, Invasive Pressure Module

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

Product Code	Classification Name	CFR Section
DQK	Diagnostic, programmable computer	870.1425
DSK	Blood pressure computer	870.1110

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™ Cardiac Output module, E-COP is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-COP Module (K922876).

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

The Datex-Ohmeda S/5™ Cardiac Output module, E-COP is a single-width plug-in parameter module for a Datex-Ohmeda S/5 modular monitoring system. E-COP is used for monitoring cardiac output (C.O.) and right ventricular ejection fraction (REF) of hospitalized patients. Invasive pressure measurement is also available. All measurements are invasive. The Datex-Ohmeda Cardiac Output module, E-COP can be used with the following Datex-Ohmeda modular monitors with 510(k) clearances:

- S/5™ Anesthesia Monitor (AM) with main software S-STD96(A) or S ARK96(A) or newer
- S/5™ Compact Anesthesia Monitor (CAM) with main software S-STD96(A) or S-ARK96(A) or newer
- S/5™ Critical Care Monitor (CCM) with main software S-ICU97(A) or newer.
- S/5™ Compact Critical Care Monitor (CCCM) with main software S-ICU97(A) or newer.

The E-COP module can be used both with the legacy S/5 8-module monitor frame F CU8 and with the new 5-module monitor frame F-CU5(P) (submitted separately). The Cardiac Output or invasive pressure signal can be displayed on the monitor screen. The waveform size, color and sweep speed can be adjusted. The E-COP module calculates a number of parameters related to oxygenation or hemodynamics. All the calculated parameters can be selected on the display, and trended. Accessories that are in contact with the patient are CE-marked by Baxter and distributed by GE Healthcare

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

Intended Use:
The Datex-Ohmeda S/5™ Cardiac Output module, E-COP and accessories are intended to be used for monitoring cardiac output (C.O.), right ventricular ejection fraction (REF), and invasive blood pressure of hospitalized patients.

Indications for use:
The Datex-Ohmeda S/5™ Cardiac Output module , E-COP and accessories are indicated for monitoring cardiac output (C.O.), right ventricular ejection fraction (REF), and invasive blood pressure of hospitalized patients.
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™ Cardiac Output module, E-COP is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-COP Module (K922876). The E-COP module has the following similarities compared to the predicate M-COP (K922876):

- The same intended use and indications for use with the addition of the REF measurement
- Identical fundamental scientific technology
- Use the same operating principle
- Identical accessories for Cardiac Output measurement
- Have the same user interface at the monitor and alarms (can be used with the same monitor software)
- The Customer and parameter specifications are the same
- Have the same safety and effectiveness
- Are manufactured using the same processes

The main differences between the new E-COP and the predicate M-COP (K922876) is primarily due to fact that the new E-COP module has the following changes:

- New color, shape, and size and thus differing mechanics
- The front panel and labeling have changed (new GE-type connector for invasive blood pressure)
- There is no Cardiac Output test connector in the front panel
- New layout of electronic input board between module connector and measurement board
- Electronic measurement board uses surface mounted instead of through-hole components
- Minor modifications and corrections to the module software, and the addition of the REF measurement.
- New invasive blood pressure accessories for the new GE-type connector

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 the Datex-Ohmeda S/5™ Cardiac Output Module, E-COP are substantially equivalent to the predicate Datex-Ohmeda M-COP Module (K922876).

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

The Datex-Ohmeda S/5™ Cardiac Output Module, E-COP and accessories has been assessed against the standards below. The device has been thoroughly tested through validation and verification of specifications.

- COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices
- FDA/DCRND Reviewer Guidance for Premarket Notification Submissions, November 1993
- IEC 60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995 (Part 1: General requirements for safety)
- EN 60601-1:1990+ A1:1993 + A13:1996 + A2:1995 (identical to IEC60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995)
- CAN/CSA C22.2 No. 601.1-M90 + S1:1994 (Canadian deviations to IEC 60601-1:1988 + Amdt. 1:1991) + S2:1998 (=IEC Amdt 2:1995)
- UL 2601-1, October 24, 1997 (U.S. deviations to IEC 60601-1:1988 + Amdt. 1:1991+ Amdt. 2:1995)
- IEC 60601-1-2:2001 (Electromagnetic compatibility – Requirements and tests)
- AAMI ES1-1993 (Safe current limits for electromedical apparatus)
- FDA/ODE Guidance for Content of Premarket Submission for Software Contained in Medical Devices. (May 11, 2005)
- ISO 14971:2000, Application of risk management to medical devices
- IEC60601-2-34 Medical electrical equipment, Part 2: Particular requirements for the safety of Direct Blood Pressure Monitoring Equipment, 2000.
- IEC 60601-2-49 Medical electrical equipment. Part 2: Particular requirements for the safety of MultifunctionPatient Monitoring Equipment: 2001.

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5™ Cardiac Output module, E-COP compared to the legally marketed (predicate) Datex-Ohmeda M-COP Module (K922876).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2006

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

Re: K052976
Trade Name: Datex-Ohmeda S/5™ Cardiac Output Module, E-COP and Accessories
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: December 15, 2005
Received: December 16, 2005

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

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): K052976

Device Name: Datex-Ohmeda S/5™ Cardiac Output module , E-COP and accessories.

Indications for use:

The Datex-Ohmeda S/5™ Cardiac Output module , E-COP and accessories are indicated for monitoring cardiac output (C.O.), right ventricular ejection fraction (REF), and invasive blood pressure of hospitalized patients.

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 K052976