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K052880

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5™ Interface Module, E-INT

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:

September 28, 2005

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

TRADE NAME:

Datex-Ohmeda S/5™ Interface Module, E-INT

COMMON NAME:

Interface Module

CLASSIFICATION NAME:

The following Class II classification appears applicable:

Product Code	Classification Name	CFR Section
MSX	System, network and communication, physiological monitors	870.2300

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™ Interface Module, E-INT is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda Interface Board B-INT (K935477).

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

The Datex-Ohmeda Interface module, E-INT is a single-width plug-in parameter module for a Datex-Ohmeda modular monitoring system. The Datex-Ohmeda S/5™ Interface module, E-INT can be used with the following Datex-Ohmeda S/5™ modular monitors:

- S/5 Anesthesia Monitor(AM) with main software S-STD93 or newer version
- S/5 Compact Anesthesia Monitor (CAM), with main S-STD93 or newer version
- S/5 Critical Care Monitor (CCM) with main software S-ICU97 or newer version
- S/5 Compact Critical Care Monitor (CCCM), with main S-ICU97 or newer version

The E-INT integrates real time and trended parameter data from external devices for viewing on the monitor display. The E-INT can integrate alarms from the Capnomac Ultima ™ and Critikon Dinamap ™ 1846SX to the Datex-Ohmeda S/5 Monitor Alarm System.

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

Intended Use:
The Datex-Ohmeda S/5™ E-INT module is used to enable integration of external measurement devices to the Datex-Ohmeda S/5 Monitors.

Indications for use:
The Datex-Ohmeda S/5™ E-INT module is indicated for integration of external measurement devices to the Datex-Ohmeda S/5 Monitors.
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™ Interface Module, E-INT is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda Interface Board B-INT (K935477).
The E-INT module has the following similarities compared to the predicate B-INT board (K935477):

- identical intended use and indications for use
- identical fundamental scientific technology
- the same (improved) electronic measurement board
- same (improved) module software
- use the same operating principle
- similar accessories (modified to fit both B-INT and E-INT)
- have the same user interface at the monitor (can be used with the same monitor software)
- the Customer and parameter specifications are the same, except for the storage temperature, which has been modified to be the same for the whole S/5 Monitor system.
- have the same safety and effectiveness
- are manufactured using the same processes

The main differences between the new E-INT module and the predicate B-INT board (K935477) is primarily due to fact that the new E-INT module has the following changes:

- Transformed the Interface board inserted into the rear of the Monitor frame to a plug-in module
- Minor improvements to the electronic measurement board
- Minor improvements to the module software
- The accessories have been modified for use both with the B-INT and E-INT module

- The separate connector for interfacing G-series gas modules and two additional channels for serial communiction have been removed as obsolete due to the evolution of the Datex-Ohmeda monitoring system since the B-INT design in 1993.
- Added interface for Dräger Julian, Cato and Cicero, for North American Dräger (NAD) ventilator models 2B & 2C, for Baxter Vigilance CCO/SvO2, Baxter Explorer CO/SvO2 and for Oximetrix 3 and Spirometry data from the Ultima monitor
- The specification for storage temperature has been modified to be the same for the whole S/5 Monitor system.

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™ Interface Module, E-INT are substantially equivalent to the predicate Datex-Ohmeda –Interface board B-INT (K935477).

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

The Datex-Ohmeda S/5™ E-INT module 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)
- FDA/ODE Guidance for Content of Premarket Submission for Software Contained in Medical Devices. (May 11, 2005)

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5™ Interface Module, E-INT compared to the legally marketed (predicate) Datex-Ohmeda Interface Board B-INT (K935477).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 2 2005

Mr. Joel Kent
Manager, Quality and Regulatory Affairs
GE Healthcare
86 Pilgrim Road
Needham, Massachusetts 02492

Re: K052880
Trade/Device Name: Datex-Ohmeda S/5™ Interface Module E-INT and accessories
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: October 11, 2005
Received: October 12, 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Datex-Ohmeda S/5™ Interface Module, E-INT and accessories.

Indications for use:

The Datex-Ohmeda S/5™ E-INT module is indicated for integration of external measurement devices to the Datex-Ohmeda S/5 Monitors.

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 Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K052880