AUG 2 3 2005

K 052145

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

July 31, 2005

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

TRADE NAME:

Datex-Ohmeda S/5™ BIS Module, E-BIS and accessories

COMMON NAME:

EEG Measurement Module with BIS Index

CLASSIFICATION NAME:

The following Class II classification appears applicable:

Product Code	Classification Name	CFR Section
GWQ	Electroencephalograph	882.1400

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™ BIS Module, E-BIS is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-BIS Module (K013389).

Declaration of Conformity to Design Controls/Fundamental Scientific Technology:

We have enclosed a copy of the Declaration of Conformity with Design Controls for the device.

There has been no change to the fundamental scientific technology from the predicate.

Classification:

The following Class II classification appears applicable:

Product Code	Classification Name	CFR Section
GWQ	Electroencephalograph	882.1400

Substantial Equivalence:

The Datex-Ohmeda S/5™ BIS Module, E-BIS is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-BIS Module (K013389).

INTENDED USE /Indications for Use

The intended use and indications for use for the modified device are the same as the predicate. The Indication For Use form on a separate page is enclosed.

Intended Use:
The Datex-Ohmeda S/5™ BIS Module, E-BIS and accessories are intended to be used with Datex-Ohmeda modular multiparameter monitors for monitoring neurophysiological status of hospitalized patients.

Indications for use:
The Datex-Ohmeda S/5™ BIS Module, E-BIS and accessories are indicated for monitoring the state of the brain by data acquisition of electroencephalograph (EEG) signals of all hospitalized patients. The Bispectral index (BIS), a processed EEG variable, may be used as an aid in monitoring the effects of certain anesthetic agents. The device is indicated for use by qualified medical personnel only.

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

The Datex-Ohmeda S/5™ BIS Module, E-BIS and accessories is a single-width plug-in parameter module for a Datex-Ohmeda modular monitoring system. The S/5 E-BIS module, M-BIS can be used with the following Datex-Ohmeda modular monitors: S/5 Anesthesia Monitor (AM), S/5 Compact Anesthesia Monitor (CAM), S/5 Critical Care Monitor (CCM) and S/5 Compact Critical Care Monitor (CCCM) with main software L-(C)ANE02(A)..00 or L-(C)ICU02(A)..00 or newer version. The Datex-Ohmeda S/5™ BIS Module, E-BIS and accessories is a parameter module for monitoring the state of the brain by data acquisition of EEG signals of all hospitalized patients. The BIS, a processed EEG variable, may be used as an aid in monitoring the effects of certain anesthetic agents. The Datex-Ohmeda S/5™ BIS Module, E-BIS and its predicate M-BIS (K013389) are used in conjunction with Aspect Medical Systems, Digital Signal Converter-Expanded Performance, DSC-XP (K011534), Patient Interface Cable; PIC (K011534), and BIS Sensor Plus (K994330), BIS Sensor XP (K002734) or BIS Sensor Pediatric (K001980).
The raw EEG signal can be displayed from one of the two monitored channels. The waveform size, color and sweep speed can be adjusted.
Calculated parameters are:

- Bispectral Index,BIS(Range=0-100),continuous processed EEG parameter correlating to the patient's level of hypnosis, where 100=awake and 0=comatose.
- Suppression Ratio,SR,(Range=0-100%), the percentage of epochs in the past 63 seconds in which the EEG signal is considered suppressed.
- Electromyograph, EMG, the absolute power (in decibels) in the frequency range 70-110 Hz
- Signal Quality Index, SQI (Range:0-100%), the percentage of good epochs in the last 60sec. that could be used to calculate the Bispectral Index and spectral variables.

All the calculated parameters can be selected on the display, and trended.
Alarms for E-BIS are taken care of by the host monitor and follow the user interface for alarms in Datex-Ohmeda S/5 patient monitors. There are auditory and visual alarms and user adjustable limits for E-BIS. The default is OFF, because it doesn't provide information to be used for treatment or therapy. The BIS Engine at BIS module dictates error messages displayed at Datex-Ohmeda's host monitor's message fields and service page. These error messages are related to the BIS measurement, but follow Datex-Ohmeda user interface rules.

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

Intended Use:
The Datex-Ohmeda S/5™ BIS Module, E-BIS and accessories are intended to be used with Datex-Ohmeda modular multiparameter monitors for monitoring neurophysiological status of hospitalized patients.

Indications for use:
The Datex-Ohmeda S/5™ BIS Module, E-BIS and accessories are indicated for monitoring the state of the brain by data acquisition of electroencephalograph (EEG) signals of all hospitalized patients. The Bispectral index (BIS), a processed EEG variable, may be used as an aid in monitoring the effects of certain anesthetic agents. 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™ BIS Module, E-BIS is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-BIS Module (K013389).

The E-BIS module has the following similarities compared to the predicate M-BIS (K013389):

- identical intended use and indications for use
- identical fundamental scientific technology
- identical electronic measurement board
- same module software (version changed from 1.0 to 1.1)
- same BIS Engine
- use the same operating principle
- identical accessories
- 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-BIS and the predicate M-BIS (K013389) is primarily due to fact that the new E-BIS module has the following changes:

- new color, shape, and size and thus differing mechanics
- The front panel and labeling have changed (added ESD symbol adjacent to BIS sensor connector)
- Minor module software change and monitor software correction

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™ BIS Module, E-BIS are substantially equivalent to the predicate Datex-Ohmeda M-BIS Module (K013389).

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

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

- 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 60601-1-1:1992 + Amdt.1:1995 (Safety requirements for medical electrical systems)
- EN 60601-1-1:1993 + A1:1996 (identical to IEC60601-1-1:1992 + Amdt.1:1995)
- AAMI ES1-1993 (Safe current limits for electromedical apparatus)
- IEC 60601-1-4:2000 (Programmable electronic medical systems)
- Electroencephalograph Devices Guidance for 510(k) Draft Document Version 1.0 November 3, 1997
- IEC 60601-2-26: 2002 Medical electrical equipment. Part 2: Particular requirements for the safety of electroencephalographs
- ISO 14971 Ed. 1: Medical devices - Application of risk management to medical devices
- AAMI TIR No.24:1999 Acquisition and use of physiologic waveform databases for testing of medical devices
- 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)
- FDA Performance standard, 21 CFR Part 898.12

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5™ BIS Module, E-BIS compared to the legally marketed (predicate) Datex-Ohmeda M-BIS Module (K013389).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2005

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

Re: K052145
Trade/Device Name: Datex-Ohmeda S/5™ BIS Module, E-BIS and accessories
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: August 5, 2005
Received: August 8, 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) 276-0115. 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/dsma/dsmamain.html

Sincerely yours,

for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052145

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

Indications for Use:

The Datex-Ohmeda S/5™ BIS Module, E-BIS and accessories are indicated for monitoring the state of the brain by data acquisition of electroencephalograph (EEG) signals of all hospitalized patients.

The Bispectral index (BIS), a processed EEG variable, may be used as an aid in monitoring the effects of certain anesthetic agents.

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)

Barbara Burns MD for Melkerson

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(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K052145