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Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5 BIS Module, M-BIS and accessories

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

COMPANY NAME/ADDRESS/PHONE/FAX:

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

NAME OF CONTACT:

Mr. Joel Kent

DATE:

October 11, 2001

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

TRADE NAME:

Datex-Ohmeda S/5 BIS Module, M-BIS and accessories

COMMON NAME:

EEG Measurement Module with BIS Index

CLASSIFICATION NAME:

The following Class II classification appears applicable:

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 BIS Module M-BIS, has been compared to a legally marketed device (predicate). A comparison is made between the Datex-Ohmeda BIS Module and the predicate device, Aspect Medical Systems Inc. BIS Engine K011534. Accessories for both the Datex-Ohmeda BIS module M-BIS, and predicate device are the same as those cleared for Aspect Medical Systems Inc under K994330, K002734 and K001980.

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

The Datex-Ohmeda BIS module, M-BIS is a single-width plug-in parameter module for a Datex-Ohmeda modular monitoring system. The Datex-Ohmeda 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-ANE02(A)..00 or L-ICU02(A)..00 or newer version.

The Datex-Ohmeda BIS module M-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 accessories: The Datex-Ohmeda BIS module, M-BIS is 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 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 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)

The Datex-Ohmeda BIS module, M-BIS and. accessories are intended to be used with Datex-Ohmeda modular multiparameter monitors for monitoring neurophysiological status of hospitalized patients.

The Datex-Ohmeda BIS module, M-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 BIS Module M-BIS, has been compared to a legally marketed device (predicate). A comparison is made between the Datex-Ohmeda BIS Module and the predicate device, Aspect Medical Systems Inc. BIS Engine K011534. Accessories for both the Datex-Ohmeda BIS module M-BIS, and predicate device are the same as those cleared for Aspect Medical Systems Inc under K994330, K002734 and K001980.

The fundamental technology of the devices are the same. The BIS engine technology (Hardware and Software) are identical compared to the predicate. The basic functions, operating principal, and signal processing are the same. Timing of the processes, handling of self tests, and DSC (Digital Signal Converter) communication are the same. Both are indicated for use in monitoring the state of the brain by data acquisition of EEG of the anesthetized patients. The BIS, a processed EEG variable, may be used as an aid in monitoring the effects of certain anesthetic agents.

Raw EEG, processed EEG variables: BIS Index, Suppression Ratio (SR), Electromyograph (EMG) and Signal Quality Index (SQI) as well as electrode impedance information are supplied by the BIS Engine to the M-BIS Module. These parameters are identical in the M-BIS module as compared to the predicate since the BIS engine generates these signals. From the user features available in the predicate device the following features are also available in the subject device, M-BIS Module: Multiple BIS smoothing rates, update rate and various filters. These user features are identical in the M-BIS module compared to the predicate. The Datex-Ohmeda BIS module, M-BIS uses identical accessories compared to the predicate Aspect Medical Systems accessories: DSC-XP (K011534), PIC Plus (K011534) and BIS Sensors: Plus (K994330), XP(K002734) and Pediatric(K001980).

The main differences in the BIS measurement in the Datex-Ohmeda BIS module, M-BIS and accessories compared with the predicate Aspect Medical Systems Inc. BIS Engine K011534 are:

The product structure: the predicate is a component for OEM (other equipment manufacturer's) devices, whereas the new device is a module inserted in a modular patient monitor. The subject device, M-BIS Module will be used with Datex-Ohmeda S/5 modular multiparameter 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-ANE02(A)..00 or L-ICU02(A)..00 or newer version. The predicate device, the BIS Engine is a small printed circuit board (PCB) that is inside the M-BIS Module. The BIS engine PCB used in M-BIS is identical to the predicate.

The Datex-Ohmeda host monitor dictates the typical common user interface for S/5 modular patient monitors including BIS module whereas Aspect Medical Systems BIS Engine has no display or printing options as a component of a larger device.
In the predicate device the available user feature, SEF, Spectral Edge Frequency, will not be shown on the Datex-Ohmeda host monitor display, because it is provided by the Datex-Ohmeda EEG module, M-EEG.
The host monitor has two kinds of display options for BIS:

- Number field with information on processed EEG variables: BIS and SR% as numbers, SQI and EMG as bars, or
- On the waveform field one raw EEG channel is displayed with number field information as described above. The EEG waveform follows the host monitor's sweep speed and scale adjustments.

The predicate device stores 24 hrs of raw EEG waveform internally whereas the new devices store only snapshots of the EEG waveform based on user input.
Alarms for BIS are taken care of by the host Datex-Ohmeda 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 BIS. The default is OFF, because it doesn't provide information to be used for treatment or therapy.
The BIS Engine dictates error messages displayed at Datex-Ohmeda's host monitor's message fields and service page. These error messages are related to BIS measurement, but follow the Datex-Ohmeda user interface.
Various Trends, graphical and numerical, as well as Trend lengths, up to 72hrs in critical care monitors and 24hrs in anesthesia monitors, are available for BIS. Trends of 20 minutes will be updated in 20 seconds and thereafter in one minute. In both anesthesia and critical care monitors short Minitrends from 5min.to 30min. can be shown on the Normal screen.

Based on the analysis and other documentation included in this 510(k) notification and attachments, it is evident that the main features, indications for use and parameter specifications of the Datex-Ohmeda BIS Module, M-BIS and accessories are substantially equivalent to the predicates Aspect Medical Systems Inc. BIS Engine K011534 and Aspect Medical Systems Inc. accessories under K994330, K002734 and K001980. The comparison shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda BIS Module M-BIS.

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

The Datex-Ohmeda S/5 BIS Module, M-BIS and accessories complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- 21 CFR 898.12 – Performance Standard for Electrode Lead Wires and Patient Cables
- 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)
- IEC60601-1-4
- Electroencephalograph Devices Guidance for 510(k) Draft Document Version 1.0 November 3, 1997
- IEC 601-2-26 Medical electrical equipment. Part 2: Particular requirements for the safety of electroencephalographs 04/01/94
- 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 (Electromagnetic compatibility - Requirements and tests), 2nd edition draft, IEC SC62A/308/CDV

Conclusion:
The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5 BIS Module, M-BIS 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

JAN 1 0 2002

Mr. Joel Kent
Manager, Quality and Regulatory Affairs
Datex-Ohmeda
86 Pilgrim Road
Needham, Massachusetts 02492

Re: K013389
Trade/Device Name: Datex-Ohmeda BIS Module, M-BIS and Accessories
Regulation Number: 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: October 11, 2001
Received: October 12, 2001

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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 Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013389

Device Name: Datex-Ohmeda BIS module, M-BIS and accessories

Indications For Use:

The Datex-Ohmeda BIS module, M-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.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013389