JUL 15 2005

K051635

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

June 17, 2005

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

TRADE NAME:

Datex-Ohmeda S/5 NeuroMuscular Transmission Module, E-NMT and Accessories.

COMMON NAME:

Neuromuscular Transmission Measurement Module and Accessories

CLASSIFICATION NAME:

The following Class II classification appears applicable:

Product Code	Classification Name	CFR Section
KOI	Electrical peripheral nerve stimulator	868.2775

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™ Neuromuscular Transmission Module, E-NMT is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M NMT Module (K955026).

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

The Datex-Ohmeda S/5 NeuroMuscular Transmission Module, E NMT and accessories are used for monitoring neuromuscular transmission (NMT) of hospitalized patients. NeuroMuscular Transmission (NMT) is the transfer of an impulse between a nerve and a muscle in the neuromuscular junction. NMT can be blocked by neuromuscular blocking agents or drugs which cause transient muscle paralysis and prevent the patient from moving and breathing spontaneously. The level of neuromuscular block is measured with the E-NMT module by stimulating a peripheral nerve, usually in the hand, and by evaluating the muscle response. For example, with the Datex-Ohmeda MechanoSensor the motion of the thumb is registered by a piezoelectric sensor, converting the physical motion to a measurable electrical signal. The intended use for the modified device is the same as for the predicate, Datex-Ohmeda M-NMT module and accessories (K955026). There has been no change to the basic technology from the predicate.. The E-NMT module is a facelifted version of the predicate M-NMT module (K955026). The module cover and mechanics have changed, but electronic measurement board is identical to the predicate device (K955026). The module software has some minor modifications for manufacturing and an enhancement saving the supramaximal current and the reference value to the NMT board EEPROM after start-up. The module software version changed from 1.0 to 2.0. The E-NMT module input board connecting the module connector to the measurement board has a minor enhancement for better defibrillation protection.

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

Intended Use:
The Datex-Ohmeda S/5™ E-NMT module is intended to be used to monitor the relaxation of the patient and regional block stimulation for nerve location.

Indications for Use:
The Datex-Ohmeda S/5™ E-NMT module is indicated for monitoring the relaxation of the patient and regional block stimulation for nerve location.
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™ Neuromuscular Transmission Module, E-NMT is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M NMT Module (K955026).

The E-NMT module has the following similarities compared to the predicate M-NMT (K955026):

- identical intended use and indications for use.
- identical fundamental scientific technology
- identical electronic measurement board
- same module software with an enhancement to save NMT data to the NMT board EEPROM after start-up.
- Can be used with the same NMT-specific monitor software. The function for storing NMT data to the EEPROM requires monitor software versions 97 or newer
- use the same operating principle
- The same accessories, and additionally a pediatric version of the mechanosensor
- have the same user interface at the monitor (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-NMT and the predicate M-NMT (K955026) is primarily due to fact that the new E-NMT module has the following changes:

- new color, shape, and size and thus differing mechanics
- The front panel and labeling have changed
- Slightly modifited module software (software version changed from 1.0 to 2.0) includes enhancement for manufacturing and saving of NMT data to the NMT board EEPROM after start-up.
- A pediatric version of the mechanosensor has been designed.
- The input board connecting the module connector to the measurement board has a minor enhancement for better defibrillation protection

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™ Neuromuscular Transmission Module, E-NMT are substantially equivalent to the predicate Datex-Ohmeda M- NMT Module (K955026).

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

The Datex-Ohmeda S/5™ Neuromuscular Transmission Module, E-NMT have 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)
- ·EC 60601-2-10:1987 + A1: 2001 Medical electrical equipment Part 2: Particular requirements for the safety or nerve and muscle stimulators
- IEC 60601-2-40:1998 Medical electrical equipment Part 2: Particular requirements for the safety of electromyographs and evoked response equipment.
- FDA Performance standard, 21 CFR Part 898.12 - PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5™ Neuromuscular Transmission Module, E-NMT is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M NMT Module (K955026) as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2005

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

Re: K051635
Trade/Device Name: Datex-Ohmeda S/5 Neuromuscular Transmission Module, E-NMT
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical peripheral nerve stimulator
Regulatory Class: II
Product Code: KOI
Dated: June 17, 2005
Received: June 20, 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 NeuroMuscular Transmission Module, E-NMT and Accessories.

Indications for Use:

The Datex-Ohmeda S/5™ E-NMT module is indicated for monitoring the relaxation of the patient and regional block stimulation for nerve location.

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: K051635