SEP - 8 2005

Premarket Notification 510(k) Summary
As required by section 807.92

Datex-Ohmeda S/5™ Tonometry Module, E TONO 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:
September 1, 2005

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

TRADE NAME:
Datex-Ohmeda S/5™ Tonometry Module, E TONO and accessories
COMMON NAME:
Regional capnometer
CLASSIFICATION NAME:
The following Class II classification appears applicable:
Product Code Classification Name CFR Section
CCK Analyzer, Gas, Carbon-Dioxide, Gaseous-phase 868.1400

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™ Tonometry Module, E-TONO is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-TONO Module (K993656).

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

The Datex-Ohmeda Tonometry module, E-TONO is a single-width plug-in parameter module for a Datex-Ohmeda modular monitoring system. The Datex-Ohmeda Tonometry module, E-TONO 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), or S/5™ Compact Critical Care Monitor (CCCM), with monitor software versions 99 or newer.

The tonometry module measures the gastrointestinal PCO2 (PgCO2) every 10 minutes utilizing a tonometry catheter placed into the patient's stomach or intestine. Initially the module fills the balloon of the Tonometrics catheter with ambient air, then repeatedly every 10 min deflates the balloon, analyzes and displays the PgCO2, and inflates the balloon again.

All the calculated parameters can be selected on the display, and trended. Alarms for Tonometry 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 Tonometry variables. The accessories are the same for the E-TONO module and the predicate device, the M-TONO (K993656).

The accessories have also been cleared separately under (K992181), (K993296), (K983366), and (K980384).

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

Intended Use:

The Datex-Ohmeda Tonometry module , E-TONO is intended to be used with Datex-Ohmeda modular monitoring systems for gastrointestinal tonometry measurements.

Indications for use:

The Datex-Ohmeda Tonometry Module is indicated for monitoring gastrointestinal CO2 (PgCO2) and calculation of various gastrointestinal tonometry parameters (gastrointestinal –arterial PCO2 difference, gastrointestinal –end-tidal PCO2 difference and intramucosal pH) when used with a Datex-Ohmeda modular monitoring system. It is indicated for use in hospital patients. The Tonometry module 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™ Tonometry Module, E-TONO is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-TONO Module (K993656).

The E-TONO module has the following similarities compared to the predicate M-TONO (K993656):

- 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)
- 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-TONO and the predicate M-TONO (K993656) is primarily due to fact that the new E-TONO module has the following changes:

- new color, shape, and size and thus differing mechanics
- The front panel and labeling have changed
- Minor modification to module software

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™ Tonometry Module, E-TONO are substantially equivalent to the predicate Datex-Ohmeda M-TONO Module (K993656).

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

Datex-Ohmeda S/5™ Tonometry Module, E TONO 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)

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5™ Tonometry Module, E-TONO when compared to the legally marketed (predicate) Datex-Ohmeda M-TONO Module (K993656).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2005

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

Re: K052167
Trade/Device Name: Datex-Ohmeda S/5™ Tonometry Module, E TONA and accessories
Regulation Number: 21 CFR §868.1400
Regulation Name: Carbon dioxide gas analyzer
Regulatory Class: II
Product Code: CCK
Dated: August 5, 2005
Received: August 9, 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 (Premarket Approval), 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ____K052167_____

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

Indications for use:

The Datex-Ohmeda Tonometry Module is indicated for monitoring gastrointestinal CO2 (PgCO2) and calculation of various gastrointestinal tonometry parameters (gastrointestinal – arterial PCO2 difference, gastrointestinal – end-tidal PCO2 difference and intramucosal pH) when used with a Datex-Ohmeda modular monitoring system. It is indicated for use in hospital patients.

The Tonometry module 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052167