K051400

JAN 20 2006

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE05 and L-ANE05A Software, using F-CU8 or F-CU5(P) Monitor Frame Options and E-EXT Extension Module and E-REC Recorder Module.

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:

May 27, 2005

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

TRADE NAME:

Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE05 and L-ANE05A Software, using F-CU8 or F-CU5(P) Monitor Frame Options and E-EXT Extension Module and E-REC Recorder Module.

COMMON NAME:

Patient Monitor
Paper Chart Recorder (E-REC)

CLASSIFICATION NAME:

The following Class II and Class I classifications appear applicable:

Product Code	Classification Name	CFR Section
MHX	Arrhythmia detector & alarm	870.1025
MLD	Monitor ST-segment & alarm	870.1025
DSF	Paper Chart Recorder	870.2810

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™ Anesthesia Monitor with L-ANE05and L-ANE05A software is substantially equivalent to the predicate Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software (K030812).

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

The S/5™ Anesthesia Monitor is a patient monitor, which displays the measurement of patient physiological parameters in the hospital setting. The measurement of patient physiological parameters is accomplished by specialized measurement modules which, when plugged into the frame, allow the modules to communicate with the monitor. The care giver can select from a variety of available measurements (parameters) and apply those parameters that are best suited to patient care. Modules perform the functions of parameter measurement and minor data processing. The S/5™ Anesthesia Monitor displays parameters on screen, signals alarms and performs advanced data processing. There are two software options available for the S/5™ Anesthesia Monitor: L-ANE05 and L-ANE05A: L-ANE05A is equipped with extended arrhythmia analysis capability. Other than arrhythmia analysis capabilities, this software option is identical to L-ANE05. There are two monitor frame options; the new 5-module F-CU5(P) monitor frame and the 8-module F-CU8 monitor frame which can be extended with an Extension Frame, F-EXT4, via the Extension Module E-EXT. The monitor can be equipped with a Recorder Module, E-REC. The S/5™ Anesthesia Monitor with L-ANE05 and L ANE05A uses several types of plug-in measurement modules. Currently, the legacy Datex-Ohmeda M-series measurement modules are used. In the future, the M-series modules will be replaced with the new E series modules, which are basically face-lifted versions of the corresponding M-series modules. Modules (with the exception of E-REC and E-EXT) are the subject of separate 510(k)'s and are not part of this notification. The S/5™ Anesthesia Monitor with L-ANE05and L-ANE05A is typically furnished with a module that measures ECG, invasive and non-invasive blood pressures, pulse oximetry and temperature. Modules are placed in the S/5 monitor frame and are automatically recognized by the monitor. The patient cables are connected to the module plug in jacks and then monitoring can begin. The S/5™ Anesthesia Monitor with L-ANE05and L-ANE05A can display measurements in the form of numeric values, traces and trends. Audible and visual alarms are used to indicate patient status. The priority profile of an alarm depends on the parameter. The S/5™ Anesthesia Monitor with L-ANE05and L-ANE05A is operated by a keyboard. Typically pressing a key results in a pop up menu appearing on the screen. Selections can then be made easily from the menu using a unique ergonomically designed pointing device on the keyboard called a ComWheel™.
The software L-ANE05and L-ANE05A perform some module related tasks like arrhythmia analysis, ST–values calculation, heart rate calculation, impedance and respiration rate calculation, energy expenditure calculation, EEG spectrum analysis evoked potential response averaging and entropy calculations. All the module communication is also handled in the main software. The software L-ANE05and L-ANE05A also include the option of creating patient care documentation. The trend information is automatically transferred to the anesthetic record, and the related events and medication can be easily entered with the same user interface as the monitor itself.
There are various optional types of keyboards, some are like standard keyboards and another is a hand-held Remote controller (REMCO) which is still directly connected to the S/5™ Anesthesia Monitor via a long cord but provides more flexibility in controlling the monitor while the doctor or nurse is handling other patient care needs. Using the Anesthesia Record Keeper software, patient related care events are documented using the keyboard. To facilitate quick access to menus, a bar code reader is also supported, although the bar code reader is not manufactured anymore.
The S/5™ Anesthesia Monitor can be in a stand-alone or networked configuration. If networked, measurements are sent to the network for central station or monitor-to-monitor viewing. Trends as well as the patient care documentation can be sent via a network to a central computer for archiving. The S/5 Anesthesia monitor can also be upgraded to L-ANE05(A) software using the S/5 L.I.F.E. upgrade program that offers a means to continuously keeping products up-to-date, by

upgrading modular anesthesia and critical care monitors and network products dating from back to 1992 to the latest S/5 software level. Upgrading of modular monitors and network products is performed with one of the available U-LIFE upgrade kits. The kit includes all hardware and software components needed to make the monitor or network product compatible with the latest main software being delivered.

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

Intended use:
The S/5™ Anesthesia Monitor with L-ANE05and L-ANE05A is intended for multiparameter patient monitoring with optional patient care documentation.
Indications for use:

The S/5™ Anesthesia Monitor with L-ANE05and L-ANE05A software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion, Bispectral index (BIS), Entropy (State Entropy and Response entropy) and neurophysiological status of all hospital patients.
The S/5™ Anesthesia Monitor with L- L-ANE05and L-ANE05A software when using BIS is for monitoring the state of the brain by data acquisition and processing of electroencephalograph signals and may be used as an aid in monitoring the effects of certain anesthetic agents.
The S/5™ Anesthesia Monitor with L- L-ANE05and L-ANE05A software is also indicated for documenting patient care related information.
The S/5™ Anesthesia Monitor with L-ANE05and L-ANE05A software 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™ Anesthesia Monitor with L-ANE05 and L-ANE05A software is substantially equivalent to the predicate device S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software (K030812). The general construction, including hardware, mechanics and software, indications for use, and intended use of the S/5™ Anesthesia Monitor with L-ANE05 and L-ANE05A software are similar to the predicate device S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software (K030812). The main difference between the AM Monitor with L-ANE05(A) software and the predicate is that the L-ANE05(A) software also supports the new 5-module F-CU5(P) frame option.
The new L-ANE05(A) software is based on the predicate L-ANE03(A) (K030812) and has basically the same functionality and the same user interface. The main differences between the the L-ANE05(A) and its predicate are (i) a new improved arrhythmia detection and analysis algorithm (ii) dynamic module addressing for some new modules not included in this submission (iii) a modification to the UPI software part to get the direct ECG waveform from the module communication, (iv) added support for the new DIS modules N-DISVENT and N-DISPICCO (v) other enhancements in communication between the monitor and other devices. The arrhythmia analysis and detection algorithm of the S/5™ Anesthesia Monitor with L-ANE05A has changed compared to the predicate device (K030812). However, the arrhythmia analysis functionality of the S/5™ Anesthesia Monitor with L-ANE05A is the same as the functionality of the predicate device S/5™ Anesthesia Monitor with L ANE03A (K030812). The S/5™ Anesthesia Monitor with L-ANE05A and the predicate alarms for the same arrhythmias in a similar manner. The S/5™ Anesthesia Monitor with L-ANE05 and L-ANE05A software is a modular multiparameter patient monitor providing connections to measurement modules. The general construction and intended use of the S/5™ Anesthesia Monitor with L-ANE05 and L-ANE05A software are the same as for the predicate S/5™ Anesthesia Monitor with L-ANE03 and L-ANE03A software (K030812).

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

The Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE05 and L-ANE05A Software, using F-CU8 or F-CU5(P) Monitor Frame Options and E-EXT Extension Module and E-REC Recorder Module have been assessed against the standards below. The device has been thoroughly tested through validation and verification of specifications.

- IEC 60601-1:1988+ Amdt.:1:1991 + Amdt. 2:1995
- EN 60601-1: 1990 + A1:1993+A2:1995+A13:1996
- CAN/CSA-C22.2 No.601.1-M90 +S1:1994+Amdt. 2:1998
- IEC 60601-2-27:1994/EN 60601-2-27:1994
- IEC 60601-2-30:1999/EN 60601-2-30:2000
- IEC 60601-2-34:2001/EN 60601-2-34:2000
- IEC 60601-2-40:1998
- IEC 60601-2-49:2001
- IEC 60601-1-2(2001)/EN 60601-1-2
- IEC 60601-1-4: 1996+Amdt. 1:1999/EN 60601-1-4
- ISO 9918:1993/EN 864:1996
- ISO 9919:1992/EN865:1997
- ISO 7767:1997/EN12598:1999
- ISO 11196:1995 + Corr. 1:1997/EN ISO11196:1997
- IEC 601-2-10:1987/EN 60601-2-10:2000 + Amd.1:2001
- IEC 60601-2-26:2002/EN60601-2-26
- EN 1060-1:1995 / EN-1060-3:1997
- EN 12470-4:2000
- IEC 60068-2
- UL 2601-1:1997
- ANSI/AAMI ES-1:1993
- ANSI/AAMI EC57:1998
- FDA 21 CFR 898.12

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE05 and L-ANE05A Software, using F-CU8 or F-CU5(P) Monitor Frame Options and E-EXT Extension Module and E-REC Recorder Module 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 20 2006

GE Healthcare
c/o Mr. Joel C. Kent
Manager, Quality and Regulatory Affairs
86 Pilgrim Road
Needham, MA 02492

Re: K051400
Trade Name: Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE05 and L-ANE05A Software, using F-CU8 or F-CU5(P) Monitor Frame Options and E-EXT Extension Module and E-REC Recorder Module.
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class II (two)
Product Code: MHX
Dated: December 21, 2005
Received: December 23, 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) 276-0210. 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,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051400

Device Name: Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE05 and L-ANE05A Software, using F-CU8 or F-CU5(P) Monitor Frame Options and E-EXT Extension Module and E-REC Recorder Module.

Indications for Use:

The Datex-Ohmeda S/5™ Anesthesia Monitor with L-ANE05 and L-ANE05A Software, using F-CU8 or F-CU5(P) Monitor Frame Options and E-EXT Extension Module and E-REC Recorder Module is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion, Bispectral index (BIS), Entropy (State Entropy and Response entropy) and neurophysiological status of all hospital patients.

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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 Cardiovascular Devices
510(k) Number K051400