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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	August 21, 2009
Submitter:	GE Healthcare Finland Oy. Kuortaneenkatu 2 Helsinki, Finland FIN-00510
Primary Contact Person:	Päivi Roiha Regulatory Affairs Leader GE Healthcare Finland Oy Kuortaneenkatu 2 Helsinki, Finland FIN-00510 Phone: + 358 10 394 3731 Fax: +358-92726532 E-mail: paivi.roiha@ge.com
Secondary Contact Person:	Robert Casarsa Regulatory Affairs Leader GE Medical Systems *Information Technologies* Phone: 414-362-3063 Fax: 414-362-2585 Robert.Casarsa@ge.com
Device: Trade Name:	Datex-Ohmeda S/5 Anesthesia Monitor with L-ANE07 and L-ANE07A software, using F-CU8 or F-CU5(P) monitor frame options and E-EXT extension module and E-REC recorder module
Common/Usual Name:	Patient Monitor, Paper Chart Recorder (E-REC)
Classification Names:	21 CFR 870.1025 Arrhythmia detector & alarm (MHX) 21 CFR 870.1025 Monitor ST-segment & alarm (MLD)
Product Code:	21 CFR 870.2810 Paper chart recorder (DSF)
Predicate Device(s):	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 (K051400)
Device Description:	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 caregiver 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-ANE07 and L-ANE07A: L-ANE07A is equipped with extended arrhythmia analysis capability. Other than

arrhythmia analysis capabilities, this software option is identical to L-ANE07. There are two monitor frame options; the 5-module F-CU5(P) monitor frame and the 8-module F-CU8 module 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-ANE07 and L-ANE07A user several types of plug-in measurement 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-ANE07 and L-ANE07A 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-ANE07 and L-ANE07A can display measurements in the form of numeric values, waveforms and trends. Audible and visual alarms are used to indicate patient status. The alarm priority of an alarm depends on the parameter. The S/5 Anesthesia Monitor with L-ANE07 and L-ANE07A is operated by a keyboard. Typically pressing a key results in a pop up menu appearing on the screen. Selections can then made easily from the menu using a unique designed pointing device on the keyboard called a ComWheel. The software L-ANE07 and L-ANE07A 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-ANE07 and L-ANE07A 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 keyboard 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 flexibility in controlling the monitor while the doctor or nurse is handling other patient care needs. Using the Anesthesia Record Keeper option, patient related care events are documented using the keyboard. 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-ANE07(A) software using the CARESCAPE Life Upgrade Program that offers a means to continuously keeping products up-to-date, by upgrading modular anesthesia dating back to 1992 to the last S/5 software level. Upgrading of modular monitors is performed with one of the available U-LIFE upgrade kits. The kit includes all hardware and main software components needed to make the monitor compatible with the last main software being delivered.

Intended Use: The Datex-Ohmeda S/5 Anesthesia Monitor with L-ANE07 or L-ANE07A software is intended for multiparameter patient monitoring with optional patient care documentation.

The S/5 Anesthesia Monitor with L-ANE07 and L-ANE07A software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion, Entropy (State Entropy and Response Entropy) and

neurophysiological status of all hospital patients.
When the BIS module is used with the S/5 Anesthesia Monitor with L-ANE07 and L-ANE07A, it is intended for use by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. The Bispectral index (BIS), a processed EEG variable, and one component of the BIS module, may be used in adults as an aid in monitoring the effects of certain anesthetic agents. The Bispectral index is a complex technology, intended for use only as an adjunct to clinical judgment and training. In addition, the clinical utility, risk/benefit, and application of BIS have not undergone full evaluation in the pediatric population.
The S/5 Anesthesia Monitor with L-ANE07 and L-ANE07A software is also indicated for documenting patient care related information.

The S/5 Anesthesia Monitor with L-ANE07 and L-ANE07A software is indicated for use by qualified medical personnel only.

Technology: The Datex-Ohmeda S/5 Anesthesia Monitor with L-ANE07 and L-ANE07A software, using F-CU8 or F-CU5(P) monitor frame options and E-EXT extension module and E-REC recorder module employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

Datex-Ohmeda S/5 Anesthesia Monitor with L-ANE07 and L-ANE07A software, using F-CU8 or F-CU5(P) monitor frame options and E-EXT extension module and E-REC recorder module and its applications comply with voluntary standards as detailed in Section 9 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (B-CPU6 verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)
- Environmental testing

Summary of Clinical Tests:

The subject of this premarket submission, Datex-Ohmeda S/5 Anesthesia Monitor with L-ANE07 and L-ANE07A software, using F-CU8 or F-CU5(P) monitor frame options and E-EXT extension module and E-REC recorder module, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Datex-Ohmeda S/5 Anesthesia Monitor with L-ANE07 and L-ANE07A software, using F-CU8 or F-CU5(P) monitor frame options and E-EXT extension module and E-REC recorder module to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

GE Healthcare Finland OY
c/o Mr. Paivi Roiha
Regulatory Affairs Leader
Kuortaneenkatu 2
Helsinki, FIN-00510
Finland

SEP 23 2009

Re: K092680
Trade/Device Name: Datex-Ohmeda S/5 Anesthesia Monitor with L-ANE07 and L-ANE07A software, using F-CU8 or F-CU5 (P) monitor frame options and E-EXT extension module and E-REC recorder module
Regulatory Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: MHX
Dated: August 30, 2009
Received: September 1, 2009

Dear Mr. Roiha:

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.

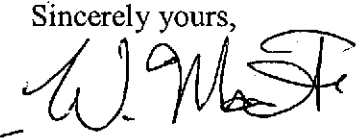
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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

Enclosure

K092680

Device Name: Datex-Ohmeda S/5 Anesthesia Monitor with L-ANE07 and L-ANE07A 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-ANE07 or L-ANE07A software is intended for multiparameter patient monitoring with optional patient care documentation.
The S/5 Anesthesia Monitor with L-ANE07 and L-ANE07A software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion, Entropy (State Entropy and Response Entropy) and neurophysiological status of all hospital patients.
When the BIS module is used with the S/5 Anesthesia Monitor with L-ANE07 and L-ANE07A, it is intended for use by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. The Bispectral index (BIS), a processed EEG variable, and one component of the BIS module, may be used in adults as an aid in monitoring the effects of certain anesthetic agents. The Bispectral index is a complex technology, intended for use only as an adjunct to clinical judgment and training. In addition, the clinical utility, risk/benefit, and application of BIS have not undergone full evaluation in the pediatric population.
The S/5 Anesthesia Monitor with L-ANE07 and L-ANE07A software is also indicated for documenting patient care related information.
The S/5 Anesthesia Monitor with L-ANE07 and L-ANE07A software is indicated for use by qualified medical personnel only.

Prescription Use_X___ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092680