K042771

OCT 15 2004

Premarket Notification 510(k) Summary
As required by section 807.92
GE Datex-Ohmeda S/5 Network and iCentral '03,Sales Revision 3.3

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:

July 28, 2004

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

TRADE NAME:

GE Datex-Ohmeda S/5 Network and iCentral '03,Sales Revision 3.3

COMMON NAME:

Clinical network and central station

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

MSX	System, network and communication, physiological monitors	870.2300

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The GE Datex-Ohmeda S/5 Network and iCentral '03 is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda S/5 Network and iCentral '03 (K033281).

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

The GE Datex-Ohmeda S/5 Network (also referred as D-O Network in the related documentation) is a system, which consists of networked devices (which have separate 510(k) clearance) and the actual networking hardware. The networked devices are Datex-Ohmeda products containing a network adapter for physical access to the D-O Network as well as software modules supporting network access. Examples of currently available networked devices are:

1. Datex-Ohmeda S/5 Anesthesia Monitor
2. Datex-Ohmeda S/5 Compact Anesthesia Monitor
3. Datex-Ohmeda S/5 Critical Care Monitor
4. Datex-Ohmeda S/5 Compact Critical Care Monitor
5. Datex-Ohmeda S/5 Light Monitor
6. Datex-Ohmeda S/5 Cardiocap 5 Monitor
7. Datex-Ohmeda S/5 WebViewer
8. Datex-Ohmeda S/5 PocketViewer/WebViewer with L-WEB03
9. GE Datex-Ohmeda S/5 Network and iCentral, included in this 510(k)

The DeioRecorder for Anesthesia (formerly named as Datex-Ohmeda AS/3 Record Keeper) is also related to the D-O Network as an application using the services provided by the D-O Network. No changes must be made to the GE Datex-Ohmeda S/5 Network and iCentral itself due to a new type of networked device. As a consequence, adding new types of Datex-Ohmeda devices to GE Datex-Ohmeda Network does not in any way affect the safety and effectiveness of GE Datex-Ohmeda Network or iCentral, if the devices are using the same protocol and the same design principles are followed as in the currently networked Datex-Ohmeda devices. In such cases, no new 510(k) application will be submitted to update the list of networked devices.
The GE Datex-Ohmeda S/5 iCentral (also referred to as D-O iCentral in the related documentation) is the primary maintainer of communication between other networked devices and is, thus, an essential part of the network. The structure and functionality of the revised network corresponds to the structure and functionality of the substantially equivalent predicate device Datex-Ohmeda Network and Central '03 (510(k) number: K033281).
The GE Datex-Ohmeda Network will be used for real-time communication between devices, for record keeping and for data management in a hospital. Practical examples of currently available features are:

* Transmission and display of measured values and alarms in the GE Datex-Ohmeda S/5 iCentral screen (central monitoring) and on the screen of another networked monitor (monitor-to-monitor communication).
* Anesthesia record keeping.
* Storing and transferring of trend and record keeping data in the network. When the patient is moved from one monitor to another, the data can be transferred with the patient. This feature includes also transferring data from/to an external system (HIS, laboratory, etc.) to/from GE Datex-Ohmeda S/5 Network.
* Storing and displaying selected waveforms over the whole patient case (Full Disclosure)
* Printing of anesthesia records, ICU reports, trend printouts, spirometry loop printouts, waveform snapshot printouts, etc.

The actual networking hardware consists of cabling, patch panels, racks, connectors, repeaters, access points with antennas etc. The networking hardware is similar to the networking hardware of the substantially equivalent predicate device Datex-Ohmeda Network and Central '03 (510(k) number: K033281).

Modifications to the predicate device Datex-Ohmeda Network and iCentral '03 K033281

1. Navigating PDF printouts based on patient names.
2. Change of the display option D-LCC19.
3. Revision change of the display option D-CFLT17.
4. Using the latest display driver for the Matrox G450 display card.
5. A new PC for the S/5 iCentral network computer.

6. Distributed patient data over several networked S/5 iCentrals.
7. Limited iCentral functionality with iCentral Client product.
8. Localization to 11 languages.
9. Compatibility with Symantec virus scanner.
10. Improved Full Disclosure printout.
11. Possibility to generate an event history printout.
12. Improved Multi View patient sector setup.
13. Possibility to define the defaults to use in a patient sector.
14. Support for Datex-Ohmeda S/5 FM monitor.
15. Improved time synchronization.

Modifications to Labeling

- Modifications to the User's Manual:
- Modifications are related to distributed patient data access and iCentral Client
- Modifications to the Technical Reference Manual:
- Modifications are related to distributed patient data access and iCentral Client

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

Intended use:
The GE Datex-Ohmeda S/5 Network and Central is intended to be used with Datex-Ohmeda devices for displaying, storing, printing and otherwise processing information received from other networked devices.
Indications for use:
The GE Datex-Ohmeda S/5TM Network and Central transfers information between networked Datex-Ohmeda devices in the Datex-Ohmeda monitor network. It also allows information transfer between several iCentrals. Within one Datex-Ohmeda monitor network it allows a networked device to display, store, print and otherwise process information received from other networked devices.
The GE Datex-Ohmeda S/5TM iCentral maintains the network connections between the Datex-Ohmeda bedside monitors and other networked devices in GE Datex-Ohmeda monitor network. Network connections consist of hardwired network cables and/or Wireless LAN (WLAN) connections. Furthermore, it coordinates the transfer of information between devices in the GE Datex-Ohmeda S/5TM Network as well as between the GE Datex-Ohmeda Network and Hospital Information Systems (HIS).
The GE Datex-Ohmeda S/5TM iCentral can be used for remote monitor management, storing, printing, viewing, reviewing or otherwise processing of information from several bedside monitors or other networked devices.
The GE Datex-Ohmeda S/5TM Network will be used for patients in the hospital and it is meant for continuous use.
The device is for use by qualified personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The GE Datex-Ohmeda S/5 Network and iCentral '03 is substantially equivalent in safety and effectiveness to the Datex-Ohmeda S/5 Network and iCentral '03 (K033281) currently in distribution.

Similarities:
The indications for use are the same as in the predicate. The intended use for the modified device is the same as for the predicate; only product name has changed from 'Datex-Ohmeda S/5 Network and iCentral' to 'GE Datex-Ohmeda S/5 Network and iCentral' (prefix 'GE' has been added). The structure and functionality of the GE Datex-Ohmeda S/5 Network and iCentral '03 closely corresponds to the structure and functionality of the Datex-Ohmeda S/5 Network and iCentral '03 (predicate). The basic architecture of GE Datex- Ohmeda S/5 Network and iCentral '03 is the same as that of Datex-Ohmeda S/5 Network and iCentral '03 (predicate).

Differences:
The following functionalities were modified
1. Navigating PDF printouts based on patient names.
2. Change of the display option D-LCC19.
3. Revision change of the display option D-CFLT17.
4. Using the latest display driver for the Matrox G450 display card.
5. A new PC for the S/5 iCentral network computer.
6. Distributed patient data over several networked S/5 iCentrals.
7. Limited iCentral functionality with iCentral Client product.
8 Localization to 11 languages.
9. Compatibility with Symantec virus scanner.
10 Improved Full Disclosure printout.
11 Possibility to generate an event history printout.
12. Improved Multi View patient sector setup.
13. Possibility to define the defaults to use in a patient sector.
14.Support for Datex-Ohmeda S/5 FM monitor.
15.Improved time synchronization.

The possible implications of these modifications to safety and effectiveness were analyzed with Risk Analysis, and the conclusion was, that they do not compromise either safety or effectiveness.

Summary:
In summary, the new GE Datex-Ohmeda S/5 Network and iCentral, described in this submission is substantially equivalent to the predicate device (K033281).

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

GE Datex-Ohmeda S/5 Network and iCentral '03,Sales Revision 3.3 complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested through validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- EN60950: 2000 (IEC60950 3rd edition) – Product Safety
- EN 55022: 1998 (IEC-CISPR 22) – Radio Frequency Interface
- EN 55024: 1998 – IT Equipment –Immunity characteristics
- EMC Directive 89/336/EEC (including amendments)
- Low Voltage Directive 73/23/EEC(amended by 93/68/EEC)
- EN 1441, Medical devices – Risk analysis
- EN 475, Medical devices - Electrically-generated alarm signals
- ISO 9703-1, ISO 9703-2, Anesthesia and respiratory care alarm signals
- IEC 60601-1-4 Medical electrical equipment. Part 1: General requirements for safety 4. Collateral Standard: Safety requirements for programmable medical systems.
- CAN/CSA-C22.2 No 60950: Information Technology Equipment Including Electrical Business Equipment
- UL60950: Information Technology Equipment Including Electrical Business Equipment
- FDA/ODE Guidance for the Content of Premarket Submission for Software Contained in Medical Devices, May 29,1998
- FDA/ODE Guidance for the Off-The-Shelf Software Use in Medical Devices, September 9, 1999
- ISO/IEC 8802-3 (ANSI/IEEE 802.3),EIA/TIA-568, EIA/TIA-TSB40,international network cabling standards
- ETS 300 826 (1997-11) – Radio Wideband Systems

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the GE Datex-Ohmeda S/5 Network and iCentral '03,Sales Revision 3.3 as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2004

Datex-Ohmeda
c/o Mr. Joel Kent
Manager, Quality and Regulatory Affairs
86 Pilgrim Road
Needham, MA 02492

Re: K042771
Trade Name: GE Datex-Ohmeda S/5 Network and iCentral `03, Sales Revicion 3.3
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: II (two)
Product Code: MSX
Dated: October 2, 2004
Received: October 5, 2004

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 (301) 594-4646. 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 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,

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

Enclosure

K042771

Indications for Use

510(k) Number (if known): _____

Device Name: GE Datex-Ohmeda S/5 Network and iCentral '03,Sales Revision 3.3

Indications for Use:

The GE Datex-Ohmeda S/5™ Network and Central transfers information between networked Datex-Ohmeda devices in the Datex-Ohmeda monitor network. It also allows information transfer between several iCentrals. Within one Datex-Ohmeda monitor network it allows a networked device to display, store, print and otherwise process information received from other networked devices.

The GE Datex-Ohmeda S/5™ iCentral maintains the network connections between the Datex-Ohmeda bedside monitors and other networked devices in GE Datex-Ohmeda monitor network. Network connections consist of hardwired network cables and/or Wireless LAN (WLAN) connections. Furthermore, it coordinates the transfer of information between devices in the GE Datex-Ohmeda S/5™ Network as well as between the GE Datex-Ohmeda Network and Hospital Information Systems (HIS).

The GE Datex-Ohmeda S/5™ iCentral can be used for remote monitor management, storing, printing, viewing, reviewing or otherwise processing of information from several bedside monitors or other networked devices.

The GE Datex-Ohmeda S/5™ Network will be used for patients in the hospital and it is meant for continuous use.

The device is for use by qualified 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 Cardiovascular Devices
510(k) Number K042771