K052972

DEC 2 9 2005

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda Network and iCentral '05,Sales Revision 4.3

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:

October 21, 2005

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

TRADE NAME:

Datex-Ohmeda Network and iCentral '05,Sales Revision 4.3

COMMON NAME:

Clinical network and central station

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

Product Code	Classification Name	CFR Section
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 Datex-Ohmeda Network and iCentral '05 is substantially equivalent in safety and effectiveness to the GE Datex-Ohmeda S/5 Network and iCentral '03 (K042771).

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

The Datex-Ohmeda 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 and GE products containing a network adapter for physical access to the D-O Network or to the GE Unity 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. GE Dash 3000, 4000 and 5000 Patient Monitor
8. GE Solar 8000M Patient Monitor
9. Datex-Ohmeda S/5 PocketViewer/WebViewer with L-WEB03
10. Datex-Ohmeda 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 Datex-Ohmeda Network and iCentral itself due to a new type of networked device. As a consequence, adding new types of Datex-Ohmeda or GE devices to Datex-Ohmeda Network and GE Unity Network does not in any way affect the safety and effectiveness of Datex-Ohmeda Network or iCentral, if the devices are using the same protocols and the same design principles are followed as in the currently networked Datex-Ohmeda Network and GE Unity Network devices. In such cases, no new 510(k) application will be submitted to update the list of networked devices.
The Datex-Ohmeda iCentral (also referred to as D-O iCentral in the related documentation) is the primary maintainer of communication between other networked devices in Datex-Ohmeda Network and is, thus, an essential part of the Datex-Ohmeda Network. The structure and functionality of the revised network corresponds to the structure and functionality of the substantially equivalent predicate device GE Datex-Ohmeda S/5 Network and iCentral '03 (510(k) number: K042771). The only addition to the predicate is that the capability to interface with GE Unity Network has been implemented this being accomplished by an additional network interface card and appropriate new software in the iCentral PC.
The 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 Datex-Ohmeda iCentral screen (central monitoring) and on the screen of another networked monitor (monitor-to-monitor communication). The source of the transferred data can be either a D-O monitor or a Unity Network monitor. In monitor-to-monitor communication the destination is always a D-O monitor.
- 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 Datex-Ohmeda 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.

All these products are also provided as part of separate upgrade products, namely U-LIFE3 & C-LIFE3 (parts of a larger S/5 L.I.F.E. upgrade program).

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

Indications for use:

The Datex-Ohmeda Network and iCentral (including iCentral Client) transfers information between networked Datex-Ohmeda devices in the Monitor Network as well as between Monitor Network and networked devices in GE Unity NetworkTM. It also allows information transfer between several iCentrals. Within one Monitor Network it allows a networked device to display, store, print and otherwise process information received from other networked devices.
The iCentral maintains the network connections between the Datex-Ohmeda bedside monitors and other networked devices in 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 Datex-Ohmeda Network, between the Datex-Ohmeda Network and devices in GE Unity Network as well as between the Datex-Ohmeda Network and Hospital Information Systems (HIS).
The 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 iCentral Client can be used for remote monitor management, printing, viewing, reviewing or otherwise processing of information from several bedside monitors or other networked devices.
The Datex-Ohmeda 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 CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda Network and iCentral '05 is substantially equivalent in safety and effectiveness to the GE Datex-Ohmeda S/5 Network and iCentral '03 (K042771) currently in distribution.

Similarities:
The indications for use are almost the same as in the predicate. The intended use for the modified device is the same as for the predicate; only the product name has changed from 'GE Datex-Ohmeda S/5 Network and iCentral' to 'Datex-Ohmeda Network and iCentral' and the ability to communicate with devices in GE Unity Network has been added. The structure and functionality of the Datex-Ohmeda Network and iCentral '05 closely corresponds to the structure and functionality of the GE Datex-Ohmeda S/5 Network and iCentral '03 (predicate). The basic architecture of Datex- Ohmeda Network and iCentral '05 is the same as that of GE Datex-Ohmeda S/5 Network and iCentral '03 (predicate).

Differences: The following functionalities were modified since the predicate device clearance of GE Datex-Ohmeda S/5 Network and iCentral '03
1. Operating system image corrections
2. Modifications related to Sales Revision 3.4
3. Modifications related to Sales Revision 3.5
4. Modifications related to Sales Revision 3.6 (in parallel with iC '05 ver 4.3)
5. Operating system image corrections
6. Modifications related to Sales Revision 4.0
7. Modifications related to Sales Revision 4.1
8. Modifications for Sales Revision 4.2

9. A new PC model HP xw4200 has been validated as the network computer C-2KNET3 for Datex-Ohmeda iCentral.
10. Modifications related to Sales Revision 4.3

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 Datex-Ohmeda Network and iCentral '05, described in this submission is substantially equivalent to the predicate device (K042771).

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

The Datex-Ohmeda Network and iCentral '05 has been assessed against the standards below. The device has been thoroughly tested through validation and verification of specifications.

- EN60950: 2000 (IEC60950 3rd edition) - Safety of information technology equipment, including electrical business equipment
- EN 55022: 1994 (IEC-CISPR 22) – Information technology equipment - Radio disturbance characteristics. Limits and methods of measurement
- EN 55024: 1998 (IEC-CISPR 24) –IT Equipment – Immunity characteristics
- EMC Directive 89/336/EEC
- Low Voltage Directive 73/23/EEC
- ISO 14971, Medical Devices – Application of risk management to medical devices
- EN 475, Medical devices - Electrically-generated alarm signals ISO 9703-1, ISO 9703-2, Anesthesia and respiratory care alarm signals
- IEC 60601-1-4Medical electrical equipment. Part 1: General requirements for safety4. 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 11, 2005
- 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 Datex-Ohmeda Network and iCentral '05 and it is substantially equivalent to the GE Datex-Ohmeda S/5 Network and iCentral '03 (K042771).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 9 2005

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

Re: K052972
Trade Name: Datex-Ohmeda Network and iCentral '05, Sales Revision 4.3
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and alarm)
Regulatory Class: Class II (two)
Product Code: MSX
Dated: December 03, 2005
Received: December 05, 2005, 2005

Dear Mr. Kent:

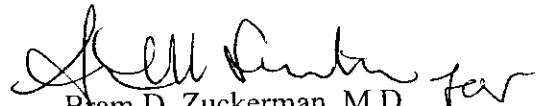
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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,



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): _____

Device Name: Datex-Ohmeda Network and iCentral '05,Sales Revision 4.3.

Indications for use:

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The 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 iCentral Client can be used for remote monitor management, printing, viewing, reviewing or otherwise processing of information from several bedside monitors or other networked devices.

The Datex-Ohmeda 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)

for Bram D Zuckerman MD

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(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052972