K052975

JAN 20 2006

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5 Web Viewer, Datex-Ohmeda S/5 Pocket Viewer and Datex-Ohmeda S/5 Cellular Viewer with L-WEB04 software

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 20, 2005

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

TRADE NAME:

Datex-Ohmeda S/5 Web Viewer, Datex-Ohmeda S/5 Pocket Viewer and Datex-Ohmeda S/5 Cellular Viewer with L-WEB04 software

COMMON NAME:

Remote monitoring device

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 revised Datex-Ohmeda S/5 Web Viewer version and S/5 Pocket Viewer version and the new S/5 Cellular Viewer are substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda S/5 Web Viewer and Datex-Ohmeda S/5 Pocket Viewer versions (K033078) currently in distribution.

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

The Datex-Ohmeda S/5 Web Viewer is a supplementary monitoring application running on a generic PC that is connected to the hospital LAN, either directly or via the Internet. It is based on the World Wide Web and Java technologies, and it is intended to be used for remote viewing of real-time patient information and trends from patient monitors that are connected to the Datex-Ohmeda S/5 Network and Central. The Pocket Viewer is a Web Viewer version running on a Pocket PC PDA that is connected to the hospital LAN via wireless access within the hospital, or via a mobile connection outside the hospital. The PDA uses a standard WLAN (802.11b) or mobile connections (GSM, GPRS, HSCSD, CDMA) to gain access to the Hospital LAN and Web Server. The Cellular Viewer is a Web Viewer version running on a generic cellular phone that is connected to the hospital LAN via a mobile connection. The mobile phone uses standard mobile connections (GSM, GPRS, HSCSD) to gain access to the Hospital LAN and Web Server.
The Web Viewer, Pocket Viewer and Cellular Viewer are not primary alarm sources but decision-making support tools that offer clinicians access to the patient data also outside the patient care area. The network architecture of the S/5 Web/Pocket/Cellular Viewer system consists of the following components:

- Datex-Ohmeda S/5 Network that connects D-O monitors to one or more D O S/5 Centrals
- The Hospital LAN to which the office PCs in the hospital are connected to
- The S/5 Web Server that is connected to both of these networks
- S/5 Web Viewer client programs running in desktop and laptop PCs, S/5 Pocket Viewer client programs running in PDAs and S/5 Cellular Viewers running in generic cellular phones
- Optional VPN (virtual private network) or dial-up solutions enabling remote connection to patient monitoring data with the S/5 Web Viewer, Pocket Viewer and Cellular Viewer

The hospital is responsible for ensuring a secure and functional interface between the Datex-Ohmeda S/5 Network and the Hospital LAN, by utilizing, for example, a gateway, router, switch or firewall, as shown in the figure above. If the Web Viewer clients are not connected to a hospital Intranet, a regular hub can be used instead. Wireless LAN access points are required to connect the Pocket Viewer to the WLAN. For Cellular phones the proper subscriptions with the telephone operators are needed.

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

Indication for use for S/5 Web Viewer: The Datex-Ohmeda S/5 Web Viewer displays information received from other networked devices. It is comprised of a S/5 Web Server and S/5 Web Viewer clients. The Datex-Ohmeda S/5 Web Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network and S/5 Web Viewer clients. The S/5 Web Viewer client runs on a generic computer that is connected to the hospital local area network. The Datex-Ohmeda S/5 Web Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Datex-Ohmeda S/5 Web Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use. The Datex-Ohmeda S/5 Web Viewer is not a primary alarm source. The device is for use by qualified medical personnel only.

Indication for use for S/5 Pocket Viewer: The Datex-Ohmeda S/5 Pocket Viewer displays information received from other networked devices. It is comprised of a S/5 Web Server and S/5 Pocket Viewer clients. The Datex-Ohmeda S/5 Web Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network and S/5 Pocket Viewer clients. The S/5 Pocket Viewer client runs on a generic handheld computer that is connected to the hospital local area network. The Datex-Ohmeda S/5 Pocket Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Datex-Ohmeda S/5 Pocket Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use. The Datex-Ohmeda S/5 Pocket Viewer is not a primary alarm source. The device is for use by qualified medical personnel only.

Indication for use for S/5 Cellular Viewer: The Datex-Ohmeda S/5 Cellular Viewer displays information received from other networked devices. It is comprised of a S/5 Web Server and S/5 Cellular Viewer clients. The Datex-Ohmeda S/5 Web Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network and S/5 Cellular Viewer clients. The Datex-Ohmeda S/5 Cellular Viewer client runs on a generic cellular phone that is connected to the hospital local area network. The Datex-Ohmeda S/5 Cellular Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Datex-Ohmeda S/5 Cellular Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use. The Datex-Ohmeda S/5 CellularViewer is not a primary alarm source. 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 revised Datex-Ohmeda S/5 Web Viewer version and S/5 Pocket Viewer version and the new S/5 Cellular Viewer are substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda S/5 Web Viewer and Datex-Ohmeda S/5 Pocket Viewer versions (K033078) currently in distribution.

Similarities:

The indications for use for the S/5 Web Viewer is identical to the predicate.

The indications for use for the S/5 Pocket Viewer is identical to the predicate.

The indications for use for the S/5 Cellular Viewer is the same as in predicate S/5 Pocket Viewer except that the term 'generic handheld computer' has been replaced by a term 'generic mobile phone'.

The structure and functionality of the revised Datex-Ohmeda S/5 Web Viewer and S/5 Pocket Viewer and the new S/5 Cellular Viewer corresponds to the structure and functionality of the Datex-Ohmeda S/5 Web Viewer and S/5 Pocket Viewer (predicate). The basic architecture of the revised Datex-Ohmeda S/5 Web Viewer and S/5 Pocket Viewer and the new Cellular Viewer is the same as that of Datex-Ohmeda S/5 Web Viewer and Datex-Ohmeda S/5 Pocket Viewer (predicate).

The revised Datex-Ohmeda S/5 Web Viewer and S/5 Pocket Viewer and the new S/5 Cellular Viewer can show real-time curves, numeric information, graphical and numerical trends and visual alarms from bedside monitors just like the predicate.
The physical network components used by the revised S/5 Web Viewer and S/5 Pocket Viewer and the new S/5 Cellular Viewer are the same as in the predicate.

Differences:
The following functionality has been added to the revised Datex-Ohmeda S/5 Web Viewer, S/5 Pocket Viewer and the new S/5 Cellular Viewer:
User interface changes:

- A new viewer type Cellular Viewer is available
- Up to 30 concurrent Cellular Viewer users
- Entropy parameter numeric values and trends are provided
- User specific configurations are possible through User Configuration Pages
- User can change her/his own password
- No more support for S/5 Light Monitor trends

In addition to the functional changes, the following technical improvements have been implemented in the revised S/5 Web Viewer and S/5 Pocket Viewer:

- The new version supports standard mobile phone technology
- Support for HTTPS tunneling with advanced communication security is available
- PC hardware: A new version of the PC for the Web Server computer has been specified because manufacturing of the earlier one was discontinued

Summary:
The changes above do not effect safety and effectiveness of the system, and the new Datex-Ohmeda S/5 Web Viewer, S/5 Pocket Viewer and S/5 Cellular Viewer, described in this submission, are substantially equivalent to the predicate device.

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

Datex-Ohmeda S/5 Web Viewer, Datex-Ohmeda S/5 Pocket Viewer and Datex-Ohmeda S/5 Cellular Viewer with L-WEB04 software has been assessed against the standards below. The device has been thoroughly tested through validation and verification of specifications.

- EN60950: 2000 (IEC60950 3rd edition) – Product Safety
- EN 55022: 1998 (IEC-CISPR 22) – Radio Frequency Interface
- EN 55024: 1998 (IEC-CISPR 24) – Electromagnetic Immunity
- EN 61000-3-2:1995 + A1/A2/A14, Harmonic Currents
- EN 61000-3-3:1995, Voltage Fluctuation and Flicker
- EMC Directive 89/336/EEC (including amendments)
- Low Voltage Directive 73/23/EEC (amended by 93/68/EEC)
- ISO 14971:2000, Medical devices - Risk analysis
- 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. 60950-00: Safety on Information Technology Equipment.
- UL: IEC 60950 (1999) Third Edition.

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the revised Datex-Ohmeda S/5 Web Viewer version and S/5 Pocket Viewer version and the new S/5 Cellular Viewer and they are substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda S/5 Web Viewer and Datex-Ohmeda S/5 Pocket Viewer versions (K033078).

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: K052975
Trade Name: Datex-Ohmeda S/5 Web Viewer, Pocket Viewer and Cellular Viewer with L-WEB04 software
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Monitors Network and Communication System
Regulatory Class: Class II (two)
Product Code: MSX
Dated: December 19, 2005
Received: December 21, 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 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,

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): K052975

Device Name: Datex-Ohmeda S/5 Web Viewer, Datex-Ohmeda S/5 Pocket Viewer and Datex-Ohmeda S/5 Cellular Viewer with L-WEB04 software.

Indications for use:

Indication for use for S/5 Web Viewer: The Datex-Ohmeda S/5 Web Viewer displays information received from other networked devices. It is comprised of a S/5 Web Server and S/5 Web Viewer clients. The Datex-Ohmeda S/5 Web Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network and S/5 Web Viewer clients. The S/5 Web Viewer client runs on a generic computer that is connected to the hospital local area network. The Datex-Ohmeda S/5 Web Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Datex-Ohmeda S/5 Web Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use. The Datex-Ohmeda S/5 Web Viewer is not a primary alarm source. The device is for use by qualified medical personnel only.

Indication for use for S/5 Pocket Viewer: The Datex-Ohmeda S/5 Pocket Viewer displays information received from other networked devices. It is comprised of a S/5 Web Server and S/5 Pocket Viewer clients. The Datex-Ohmeda S/5 Web Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network and S/5 Pocket Viewer clients. The S/5 Pocket Viewer client runs on a generic handheld computer that is connected to the hospital local area network. The Datex-Ohmeda S/5 Pocket Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Datex-Ohmeda S/5 Pocket Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use. The Datex-Ohmeda S/5 Pocket Viewer is not a primary alarm source. The device is for use by qualified medical personnel only.

Indication for use for S/5 Cellular Viewer: The Datex-Ohmeda S/5 Cellular Viewer displays information received from other networked devices. It is comprised of a S/5 Web Server and S/5 Cellular Viewer clients. The Datex-Ohmeda S/5 Web Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network and S/5 Cellular Viewer clients. The Datex-Ohmeda S/5 Cellular Viewer client runs on a generic cellular phone that is connected to the hospital local area network. The Datex-Ohmeda S/5 Cellular Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Datex-Ohmeda S/5 Cellular Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use. The Datex-Ohmeda S/5 CellularViewer is not a primary alarm source. 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 K052975