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K023497

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5 Web Viewer with L-6WV02 software

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:

October 12, 2002

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

TRADE NAME:

Datex-Ohmeda S/5 Web Viewer with L-6WV02 software

COMMON NAME:

Remote monitoring device

CLASSIFICATION NAME:

The following Class II classification appears 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 revised Datex-Ohmeda S/5 Web Viewer with L-6WV02 software version is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda S/5 Web Viewer version (K013387).

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

The intended use for the modified device Datex-Ohmeda S/5 Web Viewer with L-6WV02 software is the same as the predicate, Datex-Ohmeda S/5 Web Viewer (K013387). There has been no change to the basic technology from the predicate. The Datex-Ohmeda S/5 Web Viewer is a supplementary monitor 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 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 product is not a primary alarm source but a decision-making support tool that offers clinicians access to the patient data outside the patient care area.
The network architecture of the S/5 Web Viewer system consists of the following components

- Datex-Ohmeda S/5 Network that connects Datex-Ohmeda monitors to one or more Datex Ohmeda S/5 Centrals.
- The Hospital LAN network to which the desktop and laptop PC's in the hospital are connected to.
- The S/5 Web Server that is connected to both of these networks that provides the S/5 Web Viewer clients with patient monitoring data from the D-O monitors.
- S/5 Web Viewer client programs running in desktop and laptop PC's
- Optionally VPN (virtual private network) or dial-up solutions enabling remote connection to patient monitoring data with the S/5 Web Viewer.

Modifications to the predicate device (Datex-Ohmeda S/5 Web Viewer, K013387) include:

PC hardware: A new version of the PC for the Web Server computer has been specified because manufacturing of the earlier one was discontinued. The requirements for the PC have remained the same.
The revised version of Datex-Ohmeda S/5 Web Viewer software L-6WV02 adds the following features to the product:

- The user can freeze and print the real-time data of the selected patient.
- The user can print the numerical trends of the selected patient.
- Netscape Navigator browser support has been included in addition to Internet Explorer.
- The previous S/5 Web Viewer was an applet that executed inside the web browser. The revised version is an application that is browser independent.
- Support for optional VPN (virtual private network) or dial-up solutions has been added.
- The number of S/5 Centrals the Web Viewer can connect to has been increased from 4 to 8.
- System administration software has been improved.

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

Intended use:

The Datex-Ohmeda S/5 Web Viewer is intended to be used for viewing or otherwise processing of information from several bedside monitors or other networked devices.

Indications for use:

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 networked devices in 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 will 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.

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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 with L-6WV02 software version is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda S/5 Web Viewer version (K013387) currently in distribution.

Similarities:
The indications for use are the same as in the predicate.
The structure and functionality of the revised Datex-Ohmeda S/5 Web Viewer corresponds to the structure and functionality of the Datex-Ohmeda S/5 Web Viewer (predicate). The basic architecture of the revised Datex-Ohmeda S/5 Web Viewer is the same as that of Datex-Ohmeda S/5 Web Viewer (predicate).
The revised Datex-Ohmeda S/5 Web 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 and the PC hardware components used by the revised S/5 Web Viewer are the same as in the predicate.

Differences:
The following functionality has been added to the revised Datex-Ohmeda S/5 Web Viewer:

- The user can freeze and print the real-time data of the selected patient
- The user can print the numerical trends of the selected patient
- The number of S/5 Centrals the Web Viewer can connect to has been increased from 4 to 8. It is possible to view only one monitor at a time.

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

- Optional VPN (virtual private network) or dial-up solutions enabling remote connection to patient monitoring data with the S/5 Web Viewer is now supported.
- Microsoft Internet Explorer and Netscape Navigator browsers are supported by the new Web Viewer version. The previous version supported the Internet Explorer only.
- Microsoft Windows 95/98/ME/NT4.0/2000/XP and Mac OS X operating systems are supported. The previous version supported Microsoft operating systems only.
- The previous S/5 Web Viewer was an applet that executed inside the web browser. The revised version is an application that is browser independent .
- The web server software has been changed to a pure Java web server. The previous version used Microsoft IIS server software.
- The system administration has been improved.

In summary, the new Datex-Ohmeda S/5 Web Viewer with L-6WV02 software, described in this submission is substantially equivalent to the predicate device.

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

The Datex-Ohmeda S/5 Web Viewer with L-6WV02 software complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software 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

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- EN 55022: 1998 (IEC-CISPR 22) – Radio Frequency Interface
- EN 55024: 1998 (IEC-CISPR 24) – Electromagnetic Immunity
- IEC 61000-3-2, Harmonic Currents (IEC 61000-3-2)
- IEC 61000-3-3, Voltage Fluctuation and Flicker (IEC-61000-4-2)
- EN 1441, Medical devices - Risk analysis
- IEC 60601-1-4
- CAN/CSA-C22.2 No 950-95: Safety on Information Technology Equipment, Including Electrical Business Equipment
- UL1950: Information Technology Equipment Including Electrical Business Equipment
- ISO/IEC 8802-3 (ANSI/IEEE 802.3), EIA/TIA-568, EIA/TIA-TSB40, international network cabling standards

Conclusion:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5 Web Viewer with L-6WV02 software as compared to the predicate device.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 4 2002

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

Re: K023497
Trade Name: Datex-Ohmeda S/5 Web Viewer with L-6WV02 Software
Regulation Name: Cardiac Monitor
Regulation Number: 21 CFR 870.2300
Regulatory Class: Class II (two)
Product Code: MSX
Dated: October 16, 2002
Received: October 18, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

510(k) Number (if known): K023497

Device Name: Datex-Ohmeda S/5 Web Viewer with L-6WV02 software

Indications For Use:

The Datex-Ohmeda S/5 Web Viewer displays information received from other networked devices. It is comprised of an 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 networked devices in 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 will 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices

510(k) Number K023497