K061994

AUG 11 2006

Premarket Notification 510(k) Summary
As required by section 807.92

Web Viewer, Pocket Viewer and Cellular Viewer with L-WEB05 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:

July 11, 2006

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

TRADE NAME:

Web Viewer, Pocket Viewer and Cellular Viewer with L-WEB05 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2006

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

Re: K061994
Trade/Device Name: Cellular Viewer, Pocket Viewer, and Cellular Viewer
Regulation Number: 21 CFR 870.2300
Regulation Name: Network and Communicaiton Physiological System
Regulatory Class: Class II
Product Code: MSX
Dated: July 11, 2006
Received: July 14, 2006

Dear Mr. Kent:

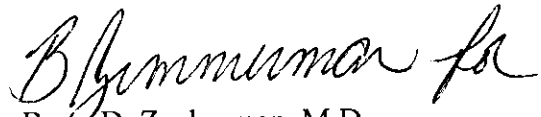
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-3150 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: **Web Viewer, Pocket Viewer and Cellular Viewer with L-WEB05 software.**

Indications for use:

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

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

Indication for use for Cellular Viewer: The Cellular Viewer displays information received from other networked devices. It is comprised of a Mobile Care Server and Cellular Viewer clients. The Mobile Care Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network or Unity Network and Cellular Viewer clients. The Cellular Viewer client runs on a generic cellular phone that is connected to the hospital local area network (LAN). The Cellular Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Cellular Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use. The Cellular Viewer 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 K061994