

510(k) Summary

NOV 12 1997

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. GENERAL INFORMATION

Establishment:

- Address: Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830
- Registration Number: 2240869
- Contact Person: Kathleen Rutherford
Manager, Regulatory Submissions
(908)321-4779, Telefax: (908)321-4841
after December 1, 1997: (732) 321-4779,
Telefax: (732) 321-4841

Device Name:

- Trade Name: SIENET Gateway product line:
MagicWeb and MagicLink I
- Classification: On November 17, 1996, FDA proposed classifications for five Medical Image Management Devices. One classification was defined as **Medical Image Communications Device** (Sec. 892.2020). This type of device was defined as Class I exempt from premarket notifications requirements only when the devices transfers images without performing irreversible or lossy compression. The SIENET gateway products that are described in this premarket notification fall within the definition of a Medical Image Communications Devices (as defined by FDA in its classification proposal).
- Performance Standards: None established under Section 514 of the Food, Drug, and Cosmetic Act

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

- **Device Description and Intended Use:**

This premarket notification covers the SIENET gateway product line, specifically, SIENET MagicLink I (ISI-Gateway) and MagicWeb (web server).

The SIENET MagicWeb and MagicLink I are medical communication devices (gateway devices). The MagicWeb is a web server intended to provide low-end image and report distribution. Images and reports can be viewed by accessing the server using commercially available Web Browsers. Images distributed by the MagicWeb are for viewing purposes and are not intended for primary diagnosis.

The MagicLink I is a gateway connection between SIENET and RIS/HIS systems. Patient demographic information and examination data (text only) are transferred across the gateway. This device is an accessory to hospital information systems.

These products support industry standard information transmission and communication protocols.

- **Technological Characteristics:**

The MagicWeb described supports DICOM 3.0, GIF, and JPEG. The MagicLink I supports DICOM 3.0 and HL7 via an OEM interface.

- **General Safety and Effectiveness Concerns:**

The device labeling contains instructions for use. It includes indications for use and any cautions. This information provides for safe and effective use of the device.

- **Substantial Equivalence:**

The SIENET gateway products, addressed in this premarket notification, are substantially equivalent to the following commercially available devices:

- Siemens: SIENET SPI Import/Export Spooler [K953522]
- Mitra Imaging: HIS-SCP (Mitra Broker)
- PixeLinks: FreePix/PixPACS [K970174]
- Autocytgroup: Amicas Web Intranet Image Server [K970064]

The SIENET gateway products described in this 510(k) have the same intended use and similar technical characteristics as the devices listed above.


Signature

8/20/97
Date



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 1997

Amy Shaw Hosler
Senior Technical Specialist
Siemens Medical Systems
186 Wood Avenue South
Iselin, NJ 08830

Re: K973131
Sienet MagicWeb and MagicLink I
Dated: August 19, 1997
Received: August 21, 1997
Regulatory class: Unclassified
Procode: 90 LMD

Dear Ms. Hosler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____
Device Name: SIENET MagicWeb & MagicLink I

Indications for Use:

The SIENET MagicWeb and MagicLink I are medical communication devices (gateway devices). The MagicWeb is a web server intended to provide low-end image and report distribution. Images and reports can be viewed by accessing the server using commercially available Web Browsers. Images distributed by the MagicWeb are for viewing purposes and are not intended for primary diagnosis.

The MagicLink I is a gateway connection between SIENET and RIS/HIS systems. Patient demographic information and examination data (text only) are transferred across the gateway. This device is an accessory to hospital information systems.

Concurrence of the CDRH, Office of Device Evaluation (ODE)

David G. Ferguson
(Division Sign-off)

Division of Reproductive Abdominal, ENT,
and Radiological Devices

510(k) Number K973131

Prescription Use OR Over-the-counter Use _____