

OCT 27 1997

K972933

510(k) Summary

J-MAC VOX/BASE System for Windows

Common classification name: Digital Image Communications System (PACS)

J-MAC Systems, Inc.
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Contact Person:

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320 Fairway Drive
Half Moon Bay, California 94019
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A. Legally Marketed Predicate Device

The J-MAC VOX/BASE for Windows is substantially equivalent to the RadWorks Medical Imaging Software (K962699) manufactured by Applicare Imaging, Inc, as well as other PACS systems. The J-MAC device is substantially equivalent to the RadWorks predicate device with regard to device features and specifications, as well as intended use. Both devices are stand alone PACS software systems with similar operating requirements, and both comply with DICOM 3.0 and ACR-NEMA 2.0. Both are Windows based applications. Both products are intended for use with Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Computed Radiography (CR), Digital Subtraction Angiography (DS), Nuclear Medicine (NM), Ultrasound (US), Endoscopy (ES), Radiographic imaging (RG), and other modalities.

B. Device Description

The J-MAC VOX/BASE for Windows is a stand alone software product which allows medical professionals to view, retrieve, store, import, process and transmit medical images over networks or phone lines. This type of product is commonly referred to as a Picture Archival and Communication System (PACS).

The software consists of four modules: Query, Receive, View and Manager. The function of each is as follows:

1. Query - This module implements the Query and Retrieve DICOM Services as a Service Class User. It calls functions in the WinSock library to connect to a remote Image Server using the TCP/IP network protocol.

2. **Receive** - This module implements the **Storage DICOM Services** as a Service Class provider. It calls functions in the WinSock library to accept connections from a remote Service Class User using the TCP/IP network protocol.
3. **View** - this module contains tools for:
 - basic image processing (flipping, rotating, inverting)
 - screen layout (cell dimensions and arrangement, colors, font)
 - image management (magnifying lens, zoom, select, hide, scroll)
4. **Manager** - This module provides a convenient way of knowing which images are already stored locally.

C. Intended Use

The device is intended to display various image data used in a hospital, clinic, physician's office and other health care settings. It handles data from CR, CT, DS, MR, NM, US, ES, RG and other modalities. The J-MAC system is an accessory to diagnostic imaging devices, it is not a diagnostic device. The J-MAC VOX/BASE System User Manual provides warnings and precautions regarding intended use, and detailed information on system operation.

D. Substantial Equivalence

	Predicate Device	Submission Device	
Product Name	RadWorks Medical Imaging Software K962699	J-MAC VOX/Base/Windows Medical Imaging Software	Substantially Equivalent
Intended Users	Medical professionals working in image analysis and management	Medical professionals working in image analysis and management	yes
Site of Use	Hospitals, clinics, remote health care facilities	Hospitals, clinics, remote health care facilities	yes
Languages	English	Japanese and English	yes
Software structure	Modular design	Modular design (4 modules: Query, Receive, View, Manager)	yes
Compliance with standards	Complies with DICOM 3.0 and ACR-NEMA 1.0 or 2.0 or proprietary	Complies with DICOM 3.0 and ACR-NEMA 1.0 or 2.0 or proprietary	yes
Operating System	Microsoft Windows NT	Microsoft Windows 95, Windows NT3 3.51, 4.0 or later	yes



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Sheila W. Pickering, Ph.D.
J-MAC Systems, Inc.
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Half Moon Bay, CA 94019

Re: K972933
VOX/BASE™ for Windows
Dated: August 5, 1997
Received: August 8, 1997
Regulatory class: Unclassified
Procode: 90 LLZ

Dear Dr. Pickering:

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

FDA Submission Cover Sheet

510(k) Number (if known): Not applicable

Device Name: J-MAC VOX/BASE for Windows

Indications For Use:

The J-MAC VOX/BASE for Windows is a stand alone software product which allows medical professionals to view, retrieve, store, import, process and transmit medical images over networks or phone lines. This type of product is commonly referred to as a Picture Archival and Communication System (PACS). It is intended to display various image data used in a hospital, clinic, physician's office and other health care settings. It handles data from CR, CT, DS, MR, NM, US, ES, RG and other modalities.

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

_____ Concurrence Of CDRH, Office Of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21CFR 801.109)

David M. Seymour
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K972933

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