AUG 3 1998

K981898

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. General Information

A. Submitted By:

MagneVu
2225 Faraday Avenue, Suite F
Carlsbad, California, 92008
Tel: (760) 929-8000
Fax: (760) 929-8100

Contact Person:

Bob Rose
Manager, Regulatory Affairs

B. Device Trade Name: OrthoVu-1000
Common Name: Magnetic Resonance Imaging System
Classification Name: Magnetic Resonance Diagnostic Device

C. Predicate Device:

ArtoScan
Ortho 8000
Rx-4000

D. Device Description:

The OrthoVu-1000 is a transportable, permanent-magnet MRI system, which uses a surface magnet/coil assembly to perform nuclear magnetic resonance imaging of human anatomy with particular emphasis on the imaging of extremities. This system utilizes a non-homogeneous magnetic field, developed by a single device head, which applies magnetic and radio frequency (RF) energy and then detects the resultant spin echoes. A computer system controls excitation and performs processing and imaging functions. The control and imaging computer as well as the associated electronics package is mounted on a cart with a magnet assembly which can be manually positioned in the correct orientation to perform the desired imaging.

E. Indications for Use:

The OrthoVu-1000 is intended to produce MRI images of human extremities, which when reviewed by a qualified medical practitioner, can render medical information of the region under review.

F. Technological Comparison:

The OrthoVu-1000 and predicate devices are intended to generate MRI images of the human body with the OrthoVu-1000, the ArtoScan and Ortho 8000, intended specifically for imaging of extremities. As with the ArtoScan and Ortho 8000 devices, the OrthoVu-1000 uses a permanent magnetic to generate the static magnetic field. The OrthoVu-1000 and predicate devices are designed to excite hydrogen nuclei and acquire data using two dimension multislice, multiecho acquisition modes. In addition, the devices reconstruct images using two dimension Fourier transform techniques.

II. Testing

The OrthoVu-1000 has been tested for conformance with NEMA standards MS1-MS8 except MS6. Further testing for conformance with applicable international standards is planned prior to release.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1998

Bob Rose
Manager, Regulatory Affairs
MagneVu
2225 Faraday Avenue, Suite F
Carlsbad, California 92008

Re: K981898
OrthoVu-1000 Magnetic Resonance Imaging System
Dated: May 27, 1998
Received: June 1, 1998
Regulatory Class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Rose:

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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

William Yin

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K981898

Device Name: OrthoVu-1000

Sponsor Name: MagneVu Inc.

Indications for Use

The OrthoVu-1000 is intended to produce MRI images of human extremities, which when reviewed by a qualified medical practitioner, can render medical information of the region under review.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☑
Over-The-Counter Use ☐

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981898