OCT 8 1999

K990153

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. Device Name:

Trade Name: *Virgo™ MRI SYSTEM*

Common Name(s): MRI System

Classification Name(s): magnetic resonance diagnostic device

2. Establishment Name & Registration Number:

Name: MILLENNIUM TECHNOLOGY, INC.
Number: Pending

3. Classification:

§ 892.1000 Magnetic resonance diagnostic device.

(a) Identification. A magnetic resonance diagnostic device is intended for general diagnostic use to present images, which reflect the spatial distribution and/or magnetic resonance spectra, which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images and/or spectra may also be produced. The device includes hydrogen-1 (proton) imaging, sodium-23 imaging, hydrogen-1 spectroscopy, phosphorus-31 spectroscopy, and chemical shift imaging (preserving simultaneous frequency and spatial information).

(b) Classification. Class II.

[53 FR 5078, Feb. 1, 1989]

Device Class: Class II
Classification Panel: Radiology Devices Panel
Product Code(s): 90LNH

4. Section 514 Compliance

MILLENNIUM TECHNOLOGY, INC. intends to comply fully with the general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

5. Performance Standards

Food and Drug Administration mandated Performance standards MRI systems are not in effect. MILLENNIUM TECHNOLOGY, INC. will comply with all voluntary Performance Standards applicable to MRI systems. At the present time, various performance standards such as ASTM, ISO, QSR/CGMP and in-house SOP standards are used.

6. *Special Controls:*

MILLENNIUM TECHNOLOGY, INC. will comply with all special controls currently in effect, including:

(a) The provisions of § 1005.1 through 1005.24 are applicable to electronic products, which are subject to the standards prescribed under this subchapter and are offered for importation into the United States.

(b) Section 1005.25 is applicable to every manufacturer of electronic products offering an electronic product for importation into the United States.

§ 1010.1 Scope. The standards listed in this subchapter are prescribed pursuant to section 358 of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f) and are applicable to electronic products as specified herein, to control electronic product radiation from such products. Standards so prescribed are subject to amendment or revocation and additional standards may be prescribed as are determined necessary for the protection of the public health and safety. [40 FR 32257, July 31, 1975]

4. *Equivalent Predicate Device:*

MILLENNIUM TECHNOLOGY, INC. believes that the *Virgo*™ MRI SYSTEM is substantially equivalent to the following MRI system:

1. AIRIS II M.R.I System, K961876, K974212, K980691 by Hitachi Medical Systems America.

The comparison device represents an MRI system that is functionally and technologically equivalent. Equivalency can be drawn with respect to the design, intended use, clinical utility and "open design" configuration. To facilitate comparison of the *Virgo*™ MRI SYSTEM to the comparison system identified above, a comparison table is provided below.

5. *Device Description:*

The *Virgo*™ MRI SYSTEM is functionally similar to most existing MRI systems. General specifications are as follows:

Magnet Subsystem
0.35 Telsa
C-Shaped Compact Permanent Magnet
Optimized Pole Design
Homogeneity +/- 10 ppm with30 cm DSV
Dimension 110cm x 160cm x 180cm
Detachable Patient Table
2nd Detachable Patient Table
Gradient Subsystem
Strength: 10mT/m
Rise Time: 0.6ms
Air Cooled
RF Subsystem
Quadrature Head Coil
Quadrature Body/Spine Coil
3 Solenoid Coils for Extremities, Shoulder and C Spine
Low Noise Preamplifier (0.5 dB Noise Figure)
Digital RF Electronics
Maximum Transmitter Power 5kW

Computer System
Host Computer: Dual Pentium CPU
True Multi-tasking NT Environment
All JAVA Language Programming
RAM: 128MB
Hard Disk: 2.1GB
Image Capacity: 9000 256x256
1.7 GB WORM Archiving
Remote System Maintenance
Console
Patient Registration
Scanning
Post-Processing & Image Enhancement (option)
Display & Analysis Package
Archiving
User Defined Protocols
User Specific Menus
View Console (option)
DICOM Compliant Laser Camera Interface
Via 3M Protoçol
Laser Camera (option)
CD Rewritable Drive (option)
Protocols
As Described on the Intended Use Page
Site Requirements
5 Gauss Line 15" x 15"
Maximum 3 Phase AC Power20kVA
No Water Requirement

6. Applicant Name & Address:

MILLENNIUM TECHNOLOGY, INC.
855 W. 12th Avenue
Vancouver, B.C., Canada V5Z1M9
604.872.6039 – 604.872.0288 fax

7. Company Contact:

Regulatory Affairs
MILLENNIUM TECHNOLOGY, INC.
855 W. 12th Avenue
Vancouver, B.C., Canada V5Z1M9
604.872.6039 – 604.872.0288 fax

8. Submission Correspondent:

Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 - fax

9. *Performance Standards:*

United States Food and Drug Administration mandated performance standards for this device do not exist. Various voluntary performance standards are utilized. Voluntary standards utilized include ASTM, Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and ISO 9000 series quality regulations.

MILLENNIUM TECHNOLOGY, INC. also meets appropriate general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

10. *Special Controls:*

MILLENNIUM TECHNOLOGY, INC. will comply with all special controls currently in effect, including:

(a) The provisions of § 1005.1 through 1005.24 are applicable to electronic products, which are subject to the standards prescribed under this subchapter and are offered for importation into the United States.

(b) Section 1005.25 is applicable to every manufacturer of electronic products offering an electronic product for importation into the United States.

§ 1010.1 Scope. The standards listed in this subchapter are prescribed pursuant to section 358 of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f) and are applicable to electronic products as specified herein, to control electronic product radiation from such products. Standards so prescribed are subject to amendment or revocation and additional standards may be prescribed as are determined necessary for the protection of the public health and safety. [40 FR 32257, July 31, 1975]

11. *Summary Comparison Table:*

FEATURE	*VIRGO MRI SYSTEM*	Hitachi	SE?
Indications for Use:	Non-invasive, non-ionizing diagnostic 2D & 3D imaging system for use on the head, spine, torso, abdomen and extremities.	Same	YES
Design:	Open MRI	Open MRI	YES
Magnetic Field:	.35T	.30T	YES
Magnet Type:	Perm.	Perm.	YES
Origin:	Canada	Japan	YES
Manufacturer:	MTI	Hitachi	YES
Product Code:	90LNH	90LNH	YES
K - Number:	PENDING	K961876, K974212, K980691	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 1999

Millenium Technology, Inc.
C/O Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
Attn: David W. Schlerf

Re: K990153
Virgo MRI System
Dated: July 5, 1999
Received: July 23, 1999
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Schlerf:

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 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). 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,

Capt. Daniel G. Schultz, M.D.
Acting 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: K990153

Device Name(s): Virgo™ MRI SYSTEM

Intended Use(s) of the Device:

Non-invasive, non-ionizing diagnostic 2D & 3D imaging system for use on the head, spine, torso, abdomen and extremities.

Diagnostic Image capabilities include:

- Sagittal section images
- Cross section & curved cross section images
- Transverse section images
- Coronal section images
- 2D Fast Spin Echo
- 2D Inversion Recovery
- 2D Fast Inversion Recovery
- 2D Dual Slice Acquisition
- 2D/3D Spin Echo
- 2D/3D Gradient Echo
- 2D/3D Gradient Echo w/ Rephasing
- 2D/3D Steady State Acquisition w/ rewind Gradient Echo (SARGE)
- MR Angiography Image Processing
- MR Angiography - Half Echo/High Resolution High Definition
- 2D/T1/T2 Weighted Imaging
- T1/T2 Proton Density Measurements

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990153

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)