MAR 2 2 2000

K994357

Attachment I
510(K) Summary
Resonance Technology, Inc M.R. Vision 2000 Ultra audio visual system

This 510(K) Summary of safety and effectiveness for the Resonance Technology, Inc M.R. Vision 2000 Ultra audio visual system is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Resonance Technology, Inc.
Address:	18121 Parthenia Street Northridge, CA 91325
Contact Person:	Mokhtar Ziarati President
Telephone:	(818) 882-1997 – Phone (818) 882-5524 - Fax
Preparation Date:	December 12, 1999
Device Trade Name:	M.R.Vision 2000 Ultra
Common Name: Classification Name:	Accessory to MRI System, Nuclear Magnetic Resonance Imaging Product Code: LNH
Legally Marketed Predicate Device:	Avocet Silent Scan K number K921891
Description of the M.R. Vision 2000 Ultra Audio Visual System / Commander X6 System	The system consists of a pair of glasses coupled with an audio transducer and noise canceling headset. The headset decreases gradient noise by up to 30 dB and includes a microphone that permits two way communication between the technologist and the patient. The video option provides an illusion of viewing a 60" screen and can be viewed in 3D. Television can be viewed with 180,000 pixels.
Intended use of the M.R. Vision 2000 Ultra Audio Visual System / Commander X6 System	The . M.R. Vision 2000 Ultra Audio Visual System / Commander X6 System is intended for use in the MRI environment to provide audio and visual to patients and thus improve patient comfort and aid in eliminating fear associated with MRI use.
Performance Data:	Study conducted by UCLS Dept of Neurology concludes M.R. Vision 2000 Ultra Audio Visual System / Commander X6 System is MRI Compatible and MRI Safe.
Conclusion:	The . M.R. Vision 2000 Ultra Audio Visual System / Commander X6 System is substantially equivalent to other existing audio visual systems used in the MRI environment in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2000

Mokhtar Ziarati
President
Resonance Technology, Inc.
18121 Parthenia Street
Northridge, CA 91325

Re: K994351
M.R. Vision 2000 Ultra Audio Visual System/
Commander X6 System
Dated: December 20, 1999
Received: December 23, 1999
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Ziarati:

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) 594-4591. 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" (21CFR 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

INDICATION FOR USE STATEMENT

510(k) Number: ~~Pending~~ K994351

Device Name **M.R. Vision 2000 Ultra Audio Visual System / Commander X6 System**

Indications for Use:

The M.R. Vision 2000 Ultra Audio Visual System / Commander X6 System is indicated for use as an accessory to the MRI environment to provide audio and visual to patients and thus improve patient comfort and aid in eliminating fear associated with MRI use.

(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 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K994351