K103507

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5. 501(k) Summary:

510(k) Section E:

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.

Submitter: Medical Visors Inc.
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Contact: Brian Hughes, President

Preparation date: 12/29/10

Product name (trade & common):
Proprietary: Medical Visors MV100
Common: Accessory to MRI

Classification name:
System: Nuclear Magnetic Resonance Imaging
Regulatory: Class II, CRF 892.1000
Product code: 90 LHN

Predicate device:
M.R. Vision 2000 Ultra, Resonance Technologies, Inc. K-994351

Device description:
Medical Visors MV100 is a self-contained video and audio entertainment system to be worn by patients during an MRI procedure. A patient wears a system comprised of video glasses and headphones unit on their head and holds a controller in their hand.

Intended use:
Medical Visors MV100 is intended for use in an MRI environment to provide audio-visual entertainment to improve patient comfort and calm patients.

The product has no medical purpose. The product operates with battery power and requires no modification to MRI facilities. The product operates in an MRI environment with no significant influence on an MRI image when used as directed, and with no harm to patients.

Device Comparison 21 CFR 807.92(a)(4)

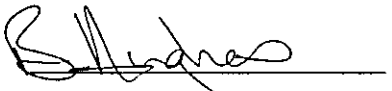
Device	**Proposed Device MEDICAL VISORS MV100**	**Predicate Device M.R. VISION 2000 ULTRA**
Intended use	Medical Visors MV100 is intended for use in an MRI environment in order to provide audio-visual entertainment to improve patient comfort and calm patients.	The M.R Vision 2000 Ultra Audio Visual System/ Commander X6 System is intended for use in an MRI environment to provide audio and visual to patients and thus improve patient comfort and aid in eliminating fear associated with MRI use.
Use environment	On patients in MRI magnetic bore.	On patients in MRI magnetic bore.
Visual display	LCD screen	LCD screen
Audio speakers	Non-magnetic speaker in headphones	Non-magnetic speaker in headphones
Electro-magnetic compatibility	RF metal shielding	RF metal shielding
Protection from heating	3/8 inch thick insulating foam	Insulating foam
Exterior material	FDA approved plastic	Unknown plastic
Entertainment source	Semiconductor memory card	External player in control room
Power source	3.2 Ah 3.8 V Li-ion battery	External power supply
Labeling	"MRI Conditional" Safety warning for abnormal operation	Unknown

Performance Data:

Study conducted by "Exponent" (www.exponent.com), an independent testing lab, concluded the Medical Visors MV100 System is MRI compatible and MRI Conditional. The Medical Visors MV100 did not exhibit any torque or displacement effects within the influence of the 3.0T static field or the spatial gradient of 5 T/m associated with the 3.0T static field. The Medical Visors MV100 can reduce MRI image intensity by more than 20% in localized areas for the MRI images. The metal surface rises less than 2ºC from RF pulses of a SAR of 2W/Kg. No metal surface comes into contact with the patients; all metal surface are heat insulated by ¾ inch silicone foam or hard plastic. The body and cable of Medical Visors MV100 System, which does come in contact with the patients, are fabricated from FDA approved materials.

An MRI with Medical Visors MV100 is equivalent to a MRI without a Medical Visors MV100, which conforms to standard for a regulatory class 892.1000 device. Medical Visors MV100 conforms to standard IEC 60601-1, "Medical Electrical Equipment—Part 1: General Requirements for Safety" and IEC 60601-2-33 (2008) "Medical Electrical Equipment - Part 2-33: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis."

Conclusion:
The Medical Visors MV100 is substantially equivalent to other existing audiovisual systems used in the MRI environment in commercial distribution.


(Signature)

Brian Hughes (Typed Name)

11/28/10 (Date)

Not issued, New product *(Premarket Notification [510(k)] Number)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Brian Hughes, PhD.
President
Medical Visors, Inc.
3834 Orchid Lane, Suite B
CALABASAS CA 91302

FEB - 8 2011

Re: K103507
Trade/Device Name: Medical Visors MV100
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: November 7, 2010
Received: November 29, 2010

Dear Dr. Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103507

Device Name: Medical Visors MV100

Indications for Use:

Medical Visors MV100 is intended for use in an MRI environment to provide audio-visual entertainment in order to improve patient comfort and calm patients.
The Medical Visors MV100 have been shown to be "MR Conditional" for field strengths up to (and including) 3T and with the MR system operating in the Normal Operating Mode (average WB SAR <2W/kg) only.

Medical Visor MV100 is not recommended for diagnostic exams of the eyes, eye canal, ear, ear canal and nose. The user is instructed to keep the control unit outside of the imaging field of view.

The patient must be given the standard ear plug hearing protection for the MRI used. The MV100 is not a hearing protection device. The MV100 should not be used if the MR noise level with ear plug protection is within 6dB of noise limit. The MV100 should not be used if the technician has critical communication with the patient, such as a lung scan.

Prescription Use ____x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K103507