JAN 2 1 2005

Inner Vision Biometrics Pty Ltd

3. 510(K) SUMMARY

SUBMITTED BY:	Inner Vision Biometrics Pty Ltd 216 Stirling Highway Claremont WA 6010 Australia
Contact in Australia:	Dr Janet Preuss Quality Assurance and Regulatory Affairs Manager Tel: +61 8 9286 5307 Fax: +61 8 9286 5399
Contact in the US:	Mr Greg Holland Regulatory Specialists Inc. 3722 Ave. Sausalito Irvine, CA 92606 Tel: 949-262-0411 Fax: 949 552 2821
DATE:	November 24 2004
NAME OF DEVICE:	R_2-MRI Analysis System
Classification Name:	System, Image Processing
Classification Number:	892.1000
Trade/Proprietary Name:	R_2-MRI Analysis System

PREDICATE DEVICE(S):

K994283: Medis, MRI (Magnetic resonance Analytical Software System)

K961969: Hitachi, Magnetic Resonance Diagnostic Device Version 6 Operating System Software

DEVICE DESCRIPTION:

Software tool used as an accessory to an MR scanning machine, to facilitate the import and visualization of multi-slice, spin-echo MRI data sets encompassing the abdomen, with functionality independent of the MRI equipment vendor, to provide objective and reproducible determination of liver parameters to support clinicians in the assessment of liver iron status.

Scientific Concepts:

The operational principle of the R_2-MRI Analysis System is based on fitting signal decay curves to the image signal intensities (e.g. of the liver) at the different echo times for the MR data set on a voxel-by-voxel (3-D pixel) basis to determine transverse relaxation rate (R_2) images, that may be further transformed by a defined calibration to provide a quantitative measure of liver iron concentrations *in vivo*.

INTENDED USE:

For the analysis of multi-slice, spin-echo MRI data sets of the liver for the measurement of liver R_2 and liver iron concentration.

SUBSTANTIAL EQUIVALENCE INFORMATION:

The device has been shown to substantially equivalent to the Medis MRI (Magnetic resonance Analytical Software System) and the Hitachi, Magnetic Resonance Diagnostic Device Version 6 Operating System Software:

	R_2-MRI Analysis System	**Medis, MRI (Magnetic resonance Analytical Software System)**	**Hitachi, Magnetic Resonance Diagnostic Device Version 6 Operating System Software**
Regulatory Class	II	II	II
510(k) number	N/A	K994283	K961969
Classification Name	System, Nuclear Magnetic Resonance Imaging, System, Image Processing Radiological	System, Image Processing	System, Nuclear Magnetic Resonance Imaging
CFR Section	892.1000	892.1000	892.1000
Product Code and Classification Panel	LNH	LNH	LNH

	R_2-MRI Analysis System	Medis, MRI (Magnetic resonance Analytical Software System)	Hitachi, Magnetic Resonance Diagnostic Device Version 6 Operating System Software
Device Name	R_2-MRI Analysis System	MRI-Magnetic Resonance Analytical Software System	Magnetic Resonance Diagnostic Device
Trade/Common Name	R_2-MRI Analysis System	MASS (Magnetic resonance Analytical Software System)	Version 6 Operating System Software
Description	Software tool to facilitate the import and visualization of multi-slice, spin-echo MRI data sets encompassing the abdomen, with functionality independent of the MRI equipment vendor, to provide objective and reproducible determination of liver parameters to support clinicians in the assessment of liver iron status.	Software tool to facilitate the import and visualization of multi-slice, multi-phase MRI data sets encompassing the cardiac chambers, with functionality independent of the MRI equipment vendor, to provide objective and reproducible determination of cardiac parameters to support clinicians in the assessment of heart function.	Revisions of a software operating system for MR scanners that "include the addition of RF spoiling, SSP for enhanced 3D MRA, RF Fat Suppression, MTC for background suppression, 3D-FSE, 3D-FIR, rephrase added to 2D-FSE and 2D-GFE, 2D-FIR Dual Contrast, RF coil uniformity image post-processing, and adaptive image post-processing" where "images may be produced in which the contrast is primarily dependent on T1 relaxation, T_2 relaxation, proton density, or a combination of all three.
Intended use	For the objective and reproducible analysis of multi-slice, spin-echo MR data sets of the liver for the measurement of liver R_2 and liver iron concentration.	For the objective and reproducible analysis of multi-slice, multi-phase left and right ventricular function from cardiac MR data sets.	" . . . intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation" of ". . . cross-sectional images that display the internal structure of the head, body, or extremities".
Intended purpose(s)	1. Supporting clinical diagnoses about the status of liver iron concentration. 2. Supporting the subsequent clinical	"1. Supporting clinical diagnoses about the status of the global and regional function and anatomy of the cardiac chambers.	"Intended to provide the physician with physiological and clinical information, obtained non-invasively." "When

	R_2-MRI Analysis System	**Medis, MRI (Magnetic resonance Analytical Software System)**	**Hitachi, Magnetic Resonance Diagnostic Device Version 6 Operating System Software**
	decision-making processes. 3. Supporting the use in clinical research trials, directed at studying changes in liver iron concentration as a result of interventions.	2. Supporting the subsequent clinical decision-making processes. 3. Supporting the use in clinical research trials, directed at studying changes in function and anatomy of the heart chambers as a result of interventions."	interpreted by a trained physician, these images provide information that can be useful in diagnosis determination." "Diagnostic uses" include "T_1, T_2, proton density measurements".
Image-type utilized	Magnetic Resonance	Magnetic Resonance	Magnetic Resonance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Inner Vision Biometrics Pty Ltd.
% Mr. Greg Holland
Regulatory Consultant
3722 Ave. Sausalito
IRVINE CA 92606

Re: K043271
Trade/Device Name: R_2-MRI Analysis System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: November 24, 2004
Received: November 26, 2004

Dear Mr. Holland:

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 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 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K043271

Device Name: R_2-MRI Analysis System

Indications For Use: The R_2-MRI Analysis System is an accessory diagnostic device to MRI scanners and is intended for diagnostic use to present images that reflect the magnetic resonance spectra for the determination of iron in the liver.

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 Device Evaluation (ODE)

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Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043271