OCT 11 2002

Section M – Special 510(k) Summary

K023130

Special 510(K) Summary

This summary of this Special 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Company Name:	MRI Devices Corporation 1515 Paramount Drive Waukesha, WI 53186
Registration Number:	2184005
Contact Person:	William Jace Dinehart jace.dinehart@mridevices.com
Telephone Number:	352.336.0010 X 154
Prepared:	September 26, 2002
Device Name:	Eloquence, Integrated Functional Imaging System
Classification Name:	Medical Specialty: Radiology,
Classification:	Class I (LNH)
Common Name:	Functional Imaging System for Magnetic Resonance Imaging System
Predicate Devices:	IFIS-SA, Integrated Functional Imaging System
Device Description:	Eloquence is a stand-alone experiment presentation and post-processing workstation. The Eloquence package supports the visualization and analysis of MRI studies based on Blood Oxygen Level Dependent (BOLD) contrast. The image contrast differs between scans as a result of the variation of blood oxygenation through task performance by the subject (e.g., finger tapping). BOLD data can be processed with Eloquence to provide analysis based on standard statistical methods.
Intended Use:	The device, Eloquence, described in this submission, provides dedicated visualization and analysis of MRI studies based on Blood Oxygen Level Dependent (BOLD) contrast which are useful for quantifying and visualizing small susceptibility changes in the human brain, created by the execution of specific tasks. These susceptibility images can

presentation of information to support the diagnostic process. These images, when interpreted by a trained physician, yield information that may assist in diagnosis.

Eloquence may also be used as a patient entertainment system, via its ability to deliver high quality audio and video to the patient.

Safety Information: No new safety hazards are introduced by the use of Eloquence.

William J. Dinehart
Manager, Functional Imaging Business
September 26, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2002

Mr. William J. Dinehart
Manager
MRI Devices Corporation
1515 Paramount Drive
WAUKESHA WI 53186

Re: K023130
Trade/Device Name: Eloquence, Integrated Functional Imaging System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: September 26, 2002
Received: October 1, 2002

Dear Mr. Dinehart:

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 (PMA), it may be subject to 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

Section C – Statement of Indications for Use:

This statement of Indications for use of this device is unchanged from that of the predicate device IFIS-SA, Integrated Functional Imaging System - K003899

Applicant: MRI Devices Corporation
510(k) number (if known): K023130
Device Name: Eloquence, Integrated Functional Imaging System

Indications for use:

To be used in conjunction with a Magnetic Resonance Scanner to analyze data acquired using Blood Oxygen Level Dependent (BOLD) contrast techniques, such analysis that can be interpreted by a trained physician.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use XX or Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023130