K061368

JUL 28 2006

510(k) Summary
for the Diagnosoft HARP
(per 21 CFR 807.92)

1. **SPONSOR**

Diagnosoft, Inc.
3461 Kenneth Dr
Palo Alto, CA 94303
Telephone: 650-320-9397
Facsimile: 253-663-0205

Primary Contact: Amr A. Awadallah
Secondary Contact: Jerry L. Prince

2. **DATE PREPARED:** February 1, 2006

3. **DEVICE NAME**

Proprietary Name: DIAGNOSOFT HARP
Common/Usual Name: HARP
Classification Name: System, Image Processing

4. **PREDICATE DEVICES**

"Cardiac Tagging Techniques/Magnetom Vision and Impact (MR accessory)," 510(k) Number K973799, Siemens Medical Solutions, USA, Inc. Decision (Substantially Equivalent) Date 01/02/1998.

5. **DEVICE DESCRIPTION**

DIAGNOSOFT HARP is a stand-alone software package, designed for the Microsoft Windows operating system, providing the capability to import, display, and analyze magnetic resonance images of the heart. HARP imports DICOM images containing anatomical MRI, tagged MRI, perfusion MRI, or delayed enhancement MRI and is independent of the MR scanner manufacturer. HARP is intended to support clinicians in the diagnosis of heart disease.

6. INTENDED USE

DIAGNOSOFT HARP is a stand-alone software package which provides the capability to review, analyze, and report on magnetic resonance (MR) images. HARP can import images from an MR system and display them in a viewing area on the computer screen. Images can be organized and displayed by study and series and organized into three-dimensional and temporal (multi-phase) collections. Temporal sequences can be displayed in a cine mode to facilitate visualization.

Tagged MR images can be imported, displayed, and analyzed. Available measurements include displacement, twist, and radial, circumferential, and principle strains. Tools are provided for display of regional motion properties of the heart.

A report interface is provided. Measurement tools provide information that can be output in standardized or specialized report formats. This interface makes it possible to quickly and reliably fill out a complete clinical report of an imaging exam. The results of the measurement tools are interpreted by the physician and can be communicated to referring physicians in supporting the determination of a diagnosis.

7. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Diagnosoft claims substantial equivalence to the visual analysis of myocardial tagging based on similarities in intended use, indications for use, principles of operation, technology, and performance. A side-by-side comparison of Siemens myocardial tagging and Diagnosoft HARP is provided in Table 1 below.

Table 2 Side-by-Side Comparison of Siemens Cardiac Tagging Visual Analysis and Diagnosoft HARP.

Vendor	Siemens	Diagnosoft
Product Name	Cardiac Tagging Techniques K973799	HARP
Intended Use	Support diagnosis	Support diagnosis
Indications for Use	Measures heart motion	Measures heart motion
Reveals myocardial motion	Yes	Yes
Assists in characterization of kinetic, hypokinetic, akinetic, and diskinetic myocardial regions	Yes	Yes
Permits regional functional analysis	Yes	Yes
Quantitative parameters viewed graphically	No	Yes
Reports containing visualization of images and quantitative parameters.	No	Yes

8. PERFORMANCE TESTING

A large body of literature exists describing the performance of HARP methods. Additional verification and validation tests were performed by Diagnosoft, Inc. to demonstrate that Diagnosoft HARP fulfills performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 28 2006

Mr. Amr A. Awadallah
President
Diagnosoft, Inc.
3461 Kenneth Dr.
PALO ALTO CA 94303

Re: K061368
Trade/Device Name: Diagnosoft Harp
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: April 15, 2006
Received: May 16, 2006

Dear Mr. Awadallah:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

510(k) Number (if known): Not Yet Assigned K061368

Device Name: DIAGNOSOFT HARP

Indications For Use:

DIAGNOSOFT HARP is a stand-alone software package which provides the capability to review, analyze, and report on magnetic resonance (MR) images. HARP can import images from an MR system and display them in a viewing area on the computer screen. Images can be organized and displayed by study and series and organized into three-dimensional and temporal (multi-phase) collections. Temporal sequences can be displayed in a cine mode to facilitate visualization.

Tagged MR images can be imported, displayed, and analyzed. Available measurements include displacement, twist, and radial, circumferential, and principle strains. Tools are provided for display of regional motion properties of the heart.

A report interface is provided. Measurement tools provide information that can be output in standardized or specialized report formats. This interface makes it possible to quickly and reliably fill out a complete clinical report of an imaging exam. The results of the measurement tools are interpreted by the physician and can be communicated to referring physicians in supporting the determination of a diagnosis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061368

Prescription Use ___X___ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)