510(K) SUMMARY

JUL 2 8 2006

510(K) Number K 061715

5.1 Applicant's Name:
INSIGHTEC-TXSONICS, LTD.
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5.2 Contact Person:
Nadir Alikacem, PhD
InSightec-TxSonics
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Dallas, TX, 75207
Tel.: 214-630-2000
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5.3 Date Prepared:
May 2006

5.4 Trade Name:
MRgFUS General Purpose and Breast Coil

5.5 Classification Name:
Magnetic Resonance Diagnostic Device

5.6 Medical Specialty:
Radiology

5.7 Product Code:
MOS

5.8 Device Class:
II

5.9 Regulation Number:
CFR 892.1000

5.10 Panel:
Radiology

5.11 Predicate Devices:

- The Medrad Breast Coil (Medrad, Inc.), K982921
- The GE 3.0T General Purpose Flex Coil (GE Medical Systems), K030953
- Pelvic Array Coil (USA Instruments, Inc.), K033753.
- The 3.0T HD Breast Array (USA Instruments, Inc.), K052585
- The GE 5 inch General Purpose Coil (GE Medical Systems), P830074, supplement number 6, LNH; Magnetic resonance diagnostic devices were reclassified by FDA from Class III to Class II, effective July 28, 1988.

5.12 Performance Standards:

- IEC 60601-1 (1988): Medical electrical equipment - Part 1: General requirements for safety, including Amendment 1 (1991) and Amendment 2 (1995).
- IEC 60601-1- 2: Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility Requirements and Tests (Second Edition, 2001).
- IEC 60601-2-33 (2002-05); Medical Electrical equipment – Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis
- UL 94; Tests for Flammability of Plastic Materials for parts in Devices and Appliance
- NEMA: MS 6 Characterization of Special Purpose Coils for Diagnostic Magnetic Resonance Images
- FDA Guidance for Diagnosis Submission of Premarket Notification for Magnetic Resonance Diagnostic Devices, FDA, CDRH

5.13 Intended Use / Indication for Use:
The MRgFUS General Purpose and Breast Coil (the MRgFUS Coil) is a receive only RF coil, designed for MR imaging of the breast and auxiliary tissue and of a variety of medium-sized anatomical regions, such as spine, neck, shoulder, thigh, foot ankle and joints.

The MRgFUS Coil is designed for use with the GE Signa™ (1.5 T or 3.0 T) MRI systems manufactured by GE Medical Systems.

5.14 Device Description:

The MRgFUS Coil is a receive-only coil. The coil is a single element coil consisting of two 6.5 inch loops located one above the other and connected electrically in parallel. Coupling of the coil to the transmitted field is prevented through three RF blocking circuits, one active and two passive circuits.

There are two versions of the MRgFUS Coil, one compatible with 1.5 T MRI and the other with 3.0T MRI, providing operating frequency of 63.8 MHz and 127.6 MHz, respectively. This difference in the operating frequency dictates different components value (i.e. capacitors and inductors). Another difference is the coil connector, which is dictated by the MRI coil interface. In all other aspects, the two coil versions are identical.

The MRgFUS Coil is specially designed for MR imaging of variety of anatomic regions including the human female breast in conjunction with a Focused UltraSound (FUS) treatment employing MR thermometry to monitor temperature. The coil provides optimum signal to noise ratio and coverage, allowing high-resolution imaging, while the sensitive region of the coil covers approximately a 15 cm Field of View.

5.15 Substantial Equivalence:

The proposed intended use and indications for use of the MRgFUS Coil are encompassed within the indications of the predicates and no new indications are claimed, as the MRgFUS Coil and its predicates are intended for MR imaging of breast or other various anatomical regions.

The MRgFUS Coil and its predicate devices also share common technological characteristics and principles of operations. Specifically, similar to its predicates, it employs the following characteristics:

- Receive-only coil
- A single coil as a basic structure component (common to the MRgFUS Coil and to both its GE 5" GP Coil and the Medrad Breast Coil predicates)
- Comparable dimensions and weight
- Compatibility with 1.5 T or 3.0 T MRI Systems
- Active and passive RF Decoupling circuits
- Employ hydrogen nuclei excitation for the imaging of the scanned organ
- Operation in conjunction with the InSightec Focused UltraSound (FUS) treatment employing MR thermometry to monitor temperature (common to the MRgFUS Coil and the Pelvic Array Coil, K033753).

- Optimal Signal to Noise Ratio (SNR) and coverage and high-resolution imaging

In addition, the MRgFUS Coil was tested to verify that it meets its specifications and conforms to the relevant recognized standards, to ensure that any minor difference between the coil and its predicates does not raise any new questions of safety and effectiveness.

Based on the safety and performance testing results, and the analysis of similarities and differences summarized above, InSightec (USA) Inc. believes that the MRgFUS Coil is substantially equivalent to its predicate devices, without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 28 2006

NAdir Alikacem, Ph.D.
Pole Manager
InSightec-TxSonics, Inc.
2777 Stemmons Frwy, Suite 940
DALLAS TX 75204

Re: K061715
Trade/Device Name: MRgFUS General Purpose and Breast Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: June 16, 2006
Received: June 22, 2006

Dear Dr. Alikacem:

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

K061715

4 INDICATIONS FOR USE STATEMENT

Following is the proposed intended use for the MRgFUS General Purpose and Breast Coil:

The MRgFUS General Purpose and Breast Coil (the MRgFUS Coil) is a receive only RF coil, designed for MR imaging of the breast and auxiliary tissue and of a variety of medium-sized anatomical regions, such as spine, neck, shoulder, thigh, foot ankle and joints.
The MRgFUS Coil is designed for use with the GE Signa™ (1.5T or 3.0T) MRI systems manufactured by GE Medical Systems.

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061715