K083434

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

A. GENERAL INFORMATION

Classification Name	Magnetic Resonance Diagnostic Device (21 CFR 892.1000)
Device Trade Name:	TTI General Purpose Coil
Applicant's Name and Address:	Tursiop Technologies, LLC 11000 Cedar Ave. Suite 280 Cleveland OH 44106
Submitter:	Raju Viswanathan Chief Technology Officer Tursiop Technologies, LLC 11000 Cedar Ave. Suite 280 Telephone: (216) 658-4521 Email: raju@tursiop.com

DEC 23 2008

B. INTENDED USE

The TT1 General Purpose Coil is a receive-only diagnostic MR imaging coil designed for use at a static magnetic field strength of 1.5T with the GE Signa® 1.5T system. It is used for obtaining diagnostic images of a variety of small-to-medium sized anatomical regions, such as jaw, spine, neck, shoulder, thigh, foot, ankle and joints.

C. DEVICE DESCRIPTION

The TT1 General Purpose Coil is a linear receive-only coil for operation at a magnetic field strength of 1.5T with the GE Signa® 1.5T system. The coil is a single element coil consisting of a 3-inch diameter loop. Coupling of the coil to the transmitted field is prevented through an active blocking circuit.

The TT1 General Purpose Coil is specially designed for MR imaging of small-to-medium sized anatomical regions, such as jaw, spine, neck, shoulder, thigh, foot, ankle and joints. The coil provides optimum signal to noise ratio and coverage, allowing high-resolution imaging, while the sensitive region of the coil covers an approximately a 10 cm Field of View.

D. PERFORMANCE TESTING & STANDARDS

- IEC 60601-1 (1988): Medical electrical equipment - Part 1: General requirements for safety, including Amendment 1 (1991) and Amendment 2 (1995).
- UL 94; Tests for Flammability of Plastic Materials for parts in Devices and Appliance
- NEMA: MS-6 (2008) Characterization of Special Purpose Coils for Diagnostic Magnetic Resonance Images
- NEMA Standardized 510(k) Pre-Market Notification Submission Template for RF Coil Accessories Intended for Use with Magnetic Resonance Diagnostic Imaging Devices

E. PREDICATE DEVICES

The TT1 General Purpose Coil is substantially equivalent to the predicate devices. The table below identifies similarities between the devices. Although the GE 3-inch General Purpose Coil is in commercial distribution it is not included in the FDA 510(k) database and/or has been purged from the FDA PMA database. Tursiop Technologies LLC has conducted side by side testing between the TT1 General Purpose Coil and the GE 3-inch General Purpose Coil to verify substantial equivalence.

Parameter	TT1 General Purpose Coil	Predicate Coil: GE 3-inch General Purpose Coil	Predicate Coil: MRgFUS General Purpose and Breast Coil (K061715)
Intended/Indications for Use	The TT1 General Purpose Coil is a receive-only diagnostic MR imaging coil designed for use at a static magnetic field strength of 1.5T with the GE Signa® 1.5T system. It is used for obtaining diagnostic images of a variety of small-to-medium sized anatomical regions, such as jaw, spine, neck, shoulder, thigh, foot, ankle and joints.	The GE 3-inch General Purpose Coil is a receive-only RF coil designed for 1.5T MR imaging of various anatomical regions, such as jaw, spine, neck, shoulder, thigh, foot, ankle and joints.	The MRgFUS General Purpose and Breast Coil is a receive-only RF coil designed for MR imaging of breast and auxiliary tissue and various medium sized anatomical regions such as spine, neck, shoulder, thigh, foot, ankle and joints. MRgFUS is designed for use with GE Signa (1.5T or 3.0T) MR Systems
Dimens	Coil length - 3 inches Coil width - 3 inches Similar in weight	Coil length - 3 inches Coil width - 3 inches Similar in weight	Coil length - 6.5 inch Similar in size and weight
Coil Architecture	Linear/Single channel receive-only for 1.5T operation	Linear/Single channel receive-only for 1.5T operation	Single channel receive-only for 1.5T or 3.0T operation
	Housing Type - ABS plastic	Housing Type - Fiberglass	n/a
	Primary Decoupling - Active/PIN diode-enabled blocking circuitry	Primary Decoupling - Active/PIN diode-enabled blocking circuitry	Active and Passive RF Decoupling circuits
Performance & Safety	IEC 60601-1 Flammability UL 94 NEMA MS6	IEC 60601-1 Flammability UL 94 NEMA MS6	IEC 60601-1 Flammability UL 94 NEMA MS6
Principles of Operation	Hydrogen nuclei excitation for imaging of the scanned organ	Hydrogen nuclei excitation for imaging of the scanned organ	Hydrogen nuclei excitation for imaging of the scanned organ

Technological Characteristics	Optimal Signal to Noise Ratio (SNR) and coverage allowing high-resolution imaging, while the sensitive region of the coil covers an approximately 10 cm Field of View.	Optimal Signal to Noise Ratio (SNR) and coverage and high resolution imaging	Optimal Signal to Noise Ratio (SNR) and coverage, allowing high-resolution imaging, while the sensitive region of the coil covers an approximately 15 cm Field of View.

F. SAFETY AND EFFECTIVENESS

Tursiop Technologies, L.L.C will comply with FDA's GMPs and the TT1 General Purpose Coil does comply with voluntary standards for safety/effectiveness (IEC 60601, UL 94) all of which mandate that components are tested to minimize hazards (electrical, mechanical, and flammability). A risk assessment (FMEA) has been conducted. Risk management practices will be utilized to assess potential risks throughout the device life cycle and mitigate unacceptable levels of risk.

Tursiop Technologies, L.L.C. has conducted testing to establish the safety and effectiveness concerning the TT1 General Purpose Coil. Side by side comparison testing was conducted with the predicate device, GE 3-inch General Purpose Coil which demonstrated substantially equivalent performance. The TT1 General Purpose Coil does not introduce any new potential safety risks and operates in a manner similar to the predicate devices.

G. SUBSTANTIAL EQUIVALENCE STATEMENT

The TT1 General Purpose Coil is substantially equivalent to the GE 3-inch General Purpose Coil and the MRgFUS General Purpose and Breast Coil (K061715).

This opinion is based on the fact that comparing the TT1 General Purpose Coil technological characteristics, coil architecture and operating principles with that of the predicate devices reveals that the devices comply with the same or equivalent standards and have the same or equivalent intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2008

Tursiop Technologies LLC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 53313

Re: K083434
Trade/Device Name: TT1 General Purpose Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: December 6, 2008
Received: December 8, 2008

Dear Mr. Job:

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 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). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083434

Device Name: **TT1 General Purpose Coil**

Indications for Use: The TT1 General Purpose Coil is a receive-only diagnostic MR imaging coil designed for use at a static magnetic field strength of 1.5T with the GE Signa® 1.5T system. It is used for obtaining diagnostic images of a variety of small-to-medium sized anatomical regions, such as jaw, spine, neck, shoulder, thigh, foot, ankle and joints.

PrescriptionUse X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083434