K033292

NOV 26 2003

510(k) Summary of Safety and Effectiveness

Device Name	Model 554HI-12 RAPID Body Coil
Applicability	Compatible with Hitachi AIRIS-Elite MR Systems
Reason for 510(k)	New device
Classification Name	Magnetic Resonance Diagnostic Device
Device Classification Panel	Radiology
Device Classification Number	892.1000
Product Code	90MOS
Common Name	Magnetic Resonance Imaging Coil
Proprietary Name	Model 554HI-12 RAPID Body Coil
Establishment Registration Number	2183683
Address of MFG Facility	IGC-Medical Advances Inc. 10437 Innovation Drive Milwaukee, WI 53226
Point of Contact	Anthony Dietzler Quality Assurance Engineer (414) 258-3808 Ext. 255
Classification	Class II
Intended Uses	
Diagnostic Uses	2D, 3D imaging, proton density, T1 and T2 weighted imaging. 2D, 3D time-of-flight, phase contrast imaging, RAPID (parallel imaging) compatibility.
Anatomic Regions	From the chest to the pelvic region – including, but not limited to the liver, spleen, pancreas, gallbladder, peritoneum, renal/adrenal structures, torso vasculature, bladder, uterus, ovaries, and prostate.

Standards

Performance Standards	None Established under Section 514	
Voluntary Safety Standards	UL 2601-1	Medical Electrical Equipment, Part I: General Requirements for Safety
	UL 94	Tests for Flammability of Plastic Materials
	IEC 601-1	General Safety Requirements for Medical Electrical Equipment

Overview

The Radiology Devices Panel considered potential concerns regarding the safe and effective operation of Magnetic Resonance Diagnostic Devices when they recommended reclassification to Class II on July 27, 1987. After reclassification, the FDA's Center for Devices and Radiological Health (CDRH) released a draft guidance document for the content and review of Magnetic Resonance Diagnostic Device premarket notification submissions that offered clarification of these concerns. Due to considerable technological advances in MRDDs, CDRH issued an updated guidance document on November 14, 1998. The following is a summary of the information contained within this premarket notification that addresses these concerns:

The Hitachi AIRIS-Elite 0.3T MRI system, operated with the Medical Advances RAPID Body Coil, is substantially equivalent to the GE Signa 0.5T system operated with the legally marketed predicate device listed in section 4.0, within the Class II definition of Magnetic Resonance Diagnostic Device with respect to the safety parameter action levels:

Safety Parameters

Maximum Static Magnetic Field:	No change due to coil
Rate of Magnetic Field Strength Change:	No change due to coil
RF Power Deposition:	No change
Acoustic Noise Levels:	No change due to coil
Biocompatibility:	No change

Imaging Performance Parameters

Specification Volume:	No change
Signal-to-Noise Ratio:	No change
Image Uniformity:	No change
Geometric Distortion:	No change
Slice Thickness and Gap:	No change
High Contrast Spatial Resolution:	No change

General Safety and Effectiveness Concerns

The device contains instructions for use. It includes indications for use, precautions, cautions, contraindications, warnings and quality assurance testing. This information assures safe and effective use of the device.

Substantial Equivalence Summary

The Hitachi AIRIS-Elite 0.3T MRI system operated with the Medical Advances RAPID Body Coil addressed in this PMN, has the same intended use and technological characteristics as the GE Signa 1.5T system operated with the identified legally marketed predicate device. The use of this coil does not affect the Hitachi AIRIS-Elite 0.3T system safety parameter specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 2003

Mr. R. Jerry Frohlich
Manager
IGC Medical Advances, Inc.
10437 Innovation Drive
MILWAUKEE WI 53226

Re: K033292
Trade/Device Name: Airis-Elite Rapid Body Coil
Model 554HI-12
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance
diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: October 10, 2003
Received: October 27, 2003

Dear Mr. Frohlich:

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 the 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" (21CFR Part 807.97) you may obtain. 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

510(k) Number (if known): K033292

Device Name: Model 554HI-12: 0.3T RAPID Body Coil

Indications for Use:

Magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA) of the musculoskeletal structures, soft tissue and vascular structures within the anatomic regions from the chest to the pelvic region.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033292

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)