FEB 26 1997

510(k) Summary of Safety and Effectiveness K964813

Device Name	Model 675GE-64 Peripheral Vascular Coil consisting of Model 665GE-64 Lower Extremity Flexible Array and Model 538GE-64 Medium General Purpose Flex Coil
Applicability	Compatible with GE Signa 1.5T MRI systems with Phased Array option
Reason for 510(k)	New device
Classification Name	Magnetic Resonance Diagnostic Device
Device Classification Panel	Radiology
Device Classification Number	892.1000
Product Code	90LNH
Common Name	Magnetic Resonance Imaging Coil
Proprietary Name	Model 675GE-64 Peripheral Vascular Coil consisting of Model 665GE-64 Lower Extremity Flexible Array and Model 538GE-64 Medium General Purpose Flex Coil
Establishment Registration Number	2183683
Address of MFG Facility	Medical Advances, Inc. 10437 Innovation Drive Milwaukee, WI 53226
Point of Contact	Thomas E. Tynes Vice President - Operations (414) 258-3808 Ext. 407
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.
Anatomic Regions	Vascular structures, soft tissue and musculosketeal structures in the lower extremities (mid-abdomen to mid-foot)

Standards

Performance Standards	None Established under Section 514	
Voluntary Safety Standards	UL 544	Medical and Dental Equipment
	UL 94	Tests for Flammability of Plastic Materials
	IEC 601-1	General Safety Requirements for Medical Electrical Equipment
	CPAI-84	Specification for Flame Resistant Material Used in Camping Tentage

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 After reclassification, the FDA's Center for Devices and Radiological Health released a draft guidance document for the content and review of Magnetic Resonance Diagnostic Device premarket notification submissions that offered clarification of these concerns. The following is a summary of the information contained within this premarket notification that addresses these concerns:

The GE 1.5T Signa MRI system operated with the Medical Advances Peripheral Vascular Coil is substantially equivalent to the same 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
Rate of Magnetic Field Strength Change:	No change
RF Power Deposition:	No change
Acoustic Noise Levels:	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 GE 1.5T Signa MRI system operated with the Medical Advances Peripheral Vascular Coil addressed in this PMN, has the same intended use and technological characteristics as the same system operated with the identified legally marketed predicate device. The use of this coil does not affect the GE Signa system safety parameter specifications.