

SEP - 5 1996

K961628

PREMARKET NOTIFICATION SUMMARY

1. **Applicant:** W.L. Gore & Associates, Inc.
4747 Beautiful Lane, Bldg II
Phoenix, AZ 85044
Phone: 602-431-0077
- Contact:** Dawn Lopez, Associate
Date of Preparation: August 20, 1996

2. **Applicant Device:** Miniflex Coil
- Common Name:** MRI Surface Coil

Classification

Name: Magnetic Resonance Imaging Accessory

3. **Predicate Devices:**

For the purposes of determining substantial equivalence cites the following as predicate devices:

Predicate Device	Reference	Manufacturer
General Purpose Flex Coil	K924349	General Electric Medical System
Phased Array Torso Coil	K911806A	General Electric Medical System

4. **Applicant Device Description:**

The Miniflex Coil is a receive-only coil designed for use with General Electric Medical System's 1.5T SIGNA MRI Scanner. The coil is designed to give better imaging quality than would be possible with the Body Coil, by maximizing signal reception by closely conforming to the specific body part to be imaged.

The physical structure of the antenna consists of two figure-eight shaped coils in a flexible, fabric-covered material. This allows the coil to bend, making it easy to wrap around the anatomy of interest. The coil is fastened to the patient with flexible straps. All patient-contact materials are biocompatible

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and were chosen to maximize patient comfort. User instructions are contained in the User Manual provided with each device.

5. Intended Use:

The Miniflex Coil is indicated for use in magnetic resonance imaging of the elbow, wrist, ankle, foot, orbits, or other body parts where a flexible coil may be employed.

6. Technological Characteristics:

The table below presents some of the basic comparative characteristics of the applicant device and its cited predicate devices:

Parameter	Applicant Device: Miniflex Coil	Predicate Device: General Purpose Flex Coil	Predicate Device: Phased Array Torso Coil
Method of Market Entry	K961628	K924349	K911806A
Patient-Contact Material	GORE-TEX® Fabric	Same	Same
Compatible MRI System	GE SIGNA 1.5T MRI Scanner	Same	Same
Mode of Operation	Receive Only	Same	Same
Method of Decoupling	Active or passive diode decoupling	Active diode decoupling	Active diode decoupling
Formation of resonant loops	Length of cable is sized to prevent formation of resonant loops	Same	Same
Potential for RF burns	<u>Coil does not transmit RF</u> - decoupling isolates elements from transmitted RF	Same	Same
Imaging Quality	Good to Excellent, compared to predicate devices	N/A	N/A