K031089

MAY - 8 2003

W. L. GORE & ASSOCIATES, INC.

750 OTTS CHAPEL ROAD • P.O. BOX 8038 • NEWARK, DE 19714-8038
PHONE: 302/368-2575 • FAX: 302/737-2819

Premarket Notification 510(k) Summary (K031089)

a. Submitter:

W. L. Gore and Associates, Inc.
750 Ott's Chapel Rd.
Newark, DE 19713

Phone: 800-441-7404

Contact: Tracy Wolf

Date Prepared: May 5, 2003

b. Name of Device:

Trade Name: GORE-FLEX™ MP8
Multipurpose Torso Array

Common Name: MRI Surface Coil

Device Name: Coil, Magnetic Resonance, Specialty

c. Identification of Predicate Devices:

The predicate device, the Cardiovascular Array, (K013810) is a ten element phased array coil. It was designed for use with GE Signa® 1.5 MRI Systems, which consist of four signal receivers.

d. Description of the Applicant Device:

The GORE-FLEX™ MP8, is a ten element phased array coil. It is for use on the upgraded GE Signa® 1.5T MRI System with EXCITE™ Technology. The applicant device, the GORE-FLEX™ MP8, has a modified Scanner Interface Connector. This modification allows the coil to take advantage of the 8 channel receiver system.

e. Intended Use:

The applicant device, the GORE-FLEX™ MP8, is intended for multiple imaging applications with GE Signa® 1.5T MRI Systems, using EXCITE™ Technology. Its large field of view will allow for images of the complete thorax, including the heart, and its associated vasculature, the

abdomen, pelvis, and spine. A specialized sub-array will provide high resolution images of the thoracic region.

f. Technical Characteristics:

The applicant device, the GORE-FLEX™ MP8, is a ten element phased array coil for use with the upgraded GE Signa® 1.5T MRI System with EXCITE™ Technology. The applicant device, the GORE-FLEX™ MP8, has a modified Scanner Interface Connector. This modification allows the coil to take advantage of the 8 channel receiver system. Only the design of the connector box has been modified to allow up to 8 loops to be used as opposed to 4 loops. The antenna loops, patient interface, and MR safe cables remain unchanged. The GORE-FLEX™ MP8, the applicant device, is designed to maximize patient safety by using active decoupling, passive decoupling, and the MR safe cable, as does the predicate device.

g. Summary of Testing:

Test data was acquired systematically on the GE Signa® 1.5T system with EXCITE™ Technology. The comparative images of the thorax and abdomen demonstrate that the GORE-FLEX™ MP8, the applicant device, has a substantially equivalent field-of-view, image clarity and signal-to-noise ratio as the Cardiovascular Array, the predicate device.

In summary, the GORE-FLEX™ MP8 Multipurpose Torso Array (applicant) and the Cardiovascular Array (predicate) utilize similar technology and materials. There are no patient safety concerns raised as a result of the clearance of the GORE-FLEX™ MP8 Multipurpose Torso Array.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2003

Ms. Tracy DeVan Wolf
Regulatory Affairs
W. L. Gore & Associates, Inc.
750 Otts Chapel Road
P.O. Box 8038
NEWARK DE 19714-8038

Re: K031089
Trade/Device Name: Gore-Flex™ MP 8 Multipurpose Torso Array
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: April 3, 2003
Received: April 7, 2003

Dear Ms. Wolf:

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 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): K031089

Device Name: GORE-FLEX™ MP8 Multipurpose Torso Array

Indications For Use:

The GORE-FLEX™ MP8 Multipurpose Torso Array is intended for multiple imaging applications with GE SignaR 1.5T MRI Systems, using EXCITE™ Technology. Its large field of view will allow for images of the complete thorax, including the heart, and its associated vasculature, the abdomen, pelvis and spine. A specialized sub-array will provide high resolution images of the thoracic region.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓

David R. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031089