K02 3679

7. Premarket Notification 510(k) Summary

NOV 18 2002

a. Submitter:

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

Telephone: 800-441-7404

Contact: Tracy Wolf

Date Prepared: October 4, 2002

b. Name of Device:

Trade Name: Gore 3.0T Torso Array

Common Name: MRI Surface Coil

Device Name: Coil, Magnetic Resonance, Specialty

c. Identification of Predicate Devices:

The GE 3.0T Transmit/Receive Body Imaging Coil (K003613) and the GE 1.5T Torso Array (K911806) are the predicate devices, which were found to be substantially equivalent through the premarket notification process. The GE 3.0T Transmit/Receive Body Imaging Coil represents a coil that is compatible with a 3 Tesla field strength MR system, capable of imaging the neck, spine, abdomen, thorax, and extremities. The body coil is built into the GE 3.0T Signa® Magnetic Resonance system, as part of the patient couch.

The GE 1.5T Torso Array represents a 4 loop phased array designed for use with GE Signa® 1.5T MR Systems, to image the thorax, abdomen, pelvis, and spine.

d. Description of the Applicant Device:

The Gore 3.0T Torso Array is a receive only phased array coil, consisting of an anterior and a posterior "paddle." The phased array design includes 4 elements in a flexible coil, which conforms to different body sizes. The coil produces high resolution images with GE Signa® 3.0T MR Systems.

e. Intended Use:

The Gore 3.0T Torso Array is intended for multiple imaging applications with GE Signa® 3.0T MR Systems. It will allow for high resolution images of the thorax, abdomen, pelvis, and spine.

f. Technical Characteristics

The Gore 3.0T Torso Array is substantially equivalent to the predicate devices with regard to intended use. This has been demonstrated by imaging a variety of anatomical locations and comparing the clinical images. The descriptive information and performance data contained within this Premarket Notification submission are sufficient to demonstrate substantial equivalence of the Gore 3.0T Torso Array (applicant device) to the GE 3.0T Transmit/Receive Body Imaging Coil and GE 1.5T Torso Array (predicate devices).

The Gore 3.0T Torso Array uses the same mode of operation, a receiving coil, as the predicate devices can employ. The GE 3.0T Transmit/Receive Body Imaging Coil can also operate as a transmitting coil. The Gore 3.0T Torso Array utilizes active decoupling as do the predicate devices. The Gore 3.0T Torso Array further enhances patient safety by including passive decoupling, and the MR safe cable.

The materials of the Gore 3.0T Torso Array (applicant) are similar to those used in the GE 1.5T Torso Array (predicate). The patient contact areas for both coils are composed of a biocompatible closed cell polyethylene foam.

In summary, the Gore 3.0T Torso Array (applicant) utilizes similar technology and materials as does the GE 3.0T Transmit/Receive Body Imaging Coil (predicate) and the GE 1.5T Torso Array and is, therefore, substantially equivalent to these devices. There are no patient safety concerns raised as a result of the clearance of the Gore 3.0T Torso Array.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 2 2002

W. L. Gore & Associates, Inc
% Mr. Mark Job
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K023679
Trade/Device Name: Gore 3.0T Torso Array
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: October 31, 2002
Received: November 1, 2002

Dear Mr. Job:

This letter corrects our substantially equivalent letter of November 18, 2002 regarding the company name in the address.

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 (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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4654. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

510(k) Number (if known): K023679

Device Name: Gore 3.0T Torso Array

Indications For Use:

The Gore 3.0T Torso Array is intended for multiple imaging applications with GE Signa(R) 3.0T MR Systems. It will allow for high resolution images of the thorax, abdomen, pelvis, and spine.

(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 A. Lyon

(Division Sign-Off)
Division of Reproductive, Gastrointestinal
and Radiological Devices
510(k) Number K023679