K02 23 95

AUG 13 2002

SCANMED® OF MEDIC, INC.

"Reducing the cost of Health care through the manufacturing of Quality, Economical Products"

510(k) Summary

1.	Manufacturer name & address:	MEDIC Inc. 6912 N. 97th Circle, Suite C Omaha, NE 68122
	Establishment Registration No.:	1932898
	Applicant/Contact Person:	Randall Jones, Dr.Eng.
	Applicant Contact Info :	Ph : 402-571-3271 Fax : 402-571-3340 Email :
	Date Prepared :	15 July 2002
2.	Device common name :	MRI Accessory\ Coil
	Specific Device Tradename :	1.5T ScanMed PV Array
	Classification:	Class II/Radiology/LNH
3.	Unmodified Device Tradename:	Lower Extremity Quadrature Detection
	Array Coil Model # 100GE1500	
	Unmodified Device 510(k) No.	K933659.

4. Device Description: The 1.5T PV Array, Catalog #155GE1501, interfaces with the G.E. 1.5 Tesla Signa® system. It has been designed and optimized to collect peripheral vascular image data in three overlapping coil groups. The multi-channel design utilizes the G.E. Phased Array Coil inputs and utilizes standard coil configuration files available on the G.E. Signa® Plasma or Mouse-Driven Screen. The coil form geometry has been formed to facilitate close coupling of the imaging coil's region-of-sensitivity to the anatomy of interest. The coil assembly comes with a comfort pad set to comfortably place the patient on the coil assembly.

5. Intended Use Statement:

Soft tissue and bone imaging of both lower extremities simultaneously as allowed by the MRI system.

Magnetic resonance peripheral angiography.

Note that the intended use is not susbstantively different than that of the unmodified device (below).

Musculoskeletal: Soft tissue and bone imaging of both lower extremities: simultaneous imaging of both knees and/or ankles.

Magnetic Resonance Angiography: Peripheral arterial studies from the inguinal canal distally to the feet.

6. The modified device has the same technological characteristics as the unmodified device with only minor changes to the size and physical orientation of the individual elements of the multi-element or multi-channel MRI antenna (coil). The materials, use, and safety features are equivalent. Both are receive-only MRI antennas so no energy is imparted to the patient.

6912 North 97th Circle
Bldg. A
Omaha, NE 68122

www.scanmed.com
e-mail: scanmed@aol.com

Phone: (402) 571-3271
(800) 721-SCAN
FAX: (402) 571-3340

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2002

Randall W. Jones, Dr. Eng.
President
MEDIC, Inc.
6912 North 97th Circle
Suite C
OMAHA NE 68122

Re: K022395
Trade/Device Name: 1.5T ScanMed PV Array
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: July 15, 2002
Received: July 23, 2002

Dear Dr. Jones:

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 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 this 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" (21 CFR Part 807.97). 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

K02 2395

Appendix A

Statement of Indications for Use

The new device labeled the 1.5T ScanMed PV Array will have no substantive change in the Indications for Use over the predicate (unmodified) device, Lower Extremity Quadrature Detection Array (k933659).

The intention of the new device is to expand the anatomical coverage provided by the device by modifying the patient-user interface in terms of altering the size and anatomical location of some of the array's individual resonators, as well as adding resonators.

The Intended Use Statements remain virtually identical to those of the Unmodified device. These statements follow.

- Soft tissue and bone imaging of both lower extremities simultaneously as allowed by the MRI system.
- Magnetic resonance peripheral angiography.

Prescription Use ✓

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022395