K01 3985

FEB 01 2002

EXHIBIT 2

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Contact: Abe van der Werf, President

November 28, 2001

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: "Machnet Bilateral Open Breast Coil"
   (Catalog # MICS-GSXX)
   Classification Name: 90 MOS, COIL, MAGNETIC RESONANCE, SPECIALTY
   Common/Usual Name: Breast Coil Array Assembly

2. Equivalent legally marketed device: This device is similar in design and identical in function to the MRI Devices Corp. Model OBC-149 Breast Array Coil K003340

3. Indications for Use (intended use):. The Machnet Bilateral Open Breast Coil, Catalog Number MICS-GSXX, is for use in conjunction with a Magnetic Resonance Scanner to produce diagnostic images of the breast and axillary tissues that can be interpreted by a trained physician

4. Description of the device: The Machnet Bilateral Open Breast Coil is designed as a bilateral open breast coil which allows clinical imaging combined with very precise multiple localizations of breast lesions and subsequently small interventional breast procedures.
   Features:
   Dual channel phased array configuration.
   Allows bilateral and unilateral imaging of the breast and surrounding tissues.
   Minimal variation of contrast across images.
   The design allows adequate reception of signals from chest wall and axilla Ergonomic design minimizes motion artifacts.
   Open coil design allows virtually all sizes of breasts to be imaged.
   Breast support and positioning devices allow controlled positioning.
   High sensitivity allows thin slices.
   Interventional MRI possible with optional device (MICS-MIA).
   Accurate (2 to 3 mm) multiple computer-assisted localizations of breast lesions (with MICS-MIAS).
   Compatibility: GE Signa® (3X-LX) 1.5T, 1.0T, 0.5T MR scanners.

MR proton imaging of female breast and surrounding tissues.
Accurate Interventional MRI possible with optional device (MICS-MIA/S).

Photo of Machnet Product

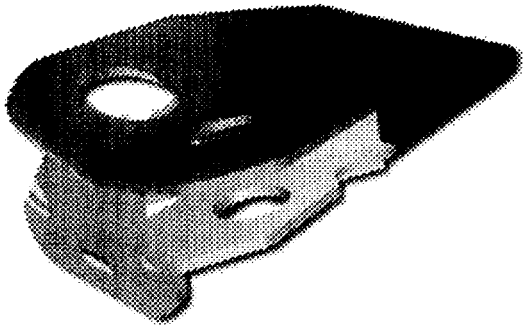
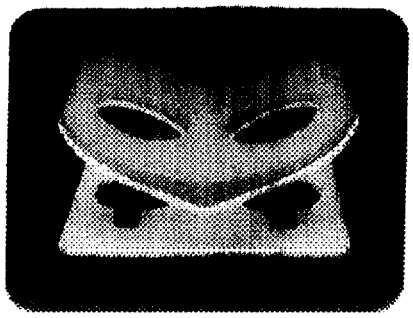


Photo of predicate device



5. Safety and Effectiveness, comparison to predicate device:

Comparison Areas	MRI Devices Corp. Model OBC-149 Breast Array Coil K003340	"Machnet Bilateral Open Breast Coil" (Catalog # MICS-GSXX)
Indications for use	In conjunction with a Magnetic Resonance Scanner to produce diagnostic images of the breast and axillary tissues that can be interpreted by a trained physician	SAME
Use with MRI Model	GE Signa	SAME
Description	See photo above	See photo above
Function	Receive only	SAME

6. Testing information and Conclusion
   In all material respects, the "Machnet Bilateral Open Breast Coil" (Catalog # MICS-GSXX) is substantially equivalent to MRI Devices Model OBC-149 (K003340). Testing was performed according to internal company procedures. Test results support the conclusion that actual device performance satisfies the design intent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 01 2002

Machnet BV
% Mr. Daniel Kamm, P.E.
Kamm & Associates
P.O. Box 7007
DEERFIELD IL 60015

Re: K013985
Trade/Device Name: Machnet Bilateral Open Breast Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: November 28, 2001
Received: December 3, 2001

Dear Mr. Kamm:

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

i) Indications for Use

510(k) Number K01 3985

The Machnet Bilateral Open Breast Coil, Catalog Number MICS-GSXX, is for use in conjunction with a Magnetic Resonance Scanner to produce diagnostic images of the breast and axillary tissues that can be interpreted by a trained physician.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over the Counter Use_____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013985