K052987

NOV - 8 2005

510(k) Summary of Safety & Effectiveness

(as required by 21 CFR 807.92c)

Date Prepared:

October 11, 2005

Submitter's Information:

NORAS RONTGEN-UND MEDIZINTECHNIK GMBH
Leibnizstrasse 4
97204 Hochberg
Germany
Phone: 49-931-299270

Trade Name, Common Name, Classification:

Trade name:	Breast Immobilization and Biopsy Device BI 160-O, BI 160-PA, and BI 160-CC
Common name:	Breast Immobilization and Biopsy Device
Classification name:	Magnetic resonance diagnostic device
Product Code:	90 LNH

Predicate Device:

DEVICE CLASSIFICATION NAME	system, nuclear magnetic resonance imaging
REGULATION NUMBER	892.1000
510(K) NUMBER	K010570
DEVICE NAME	BREAST IMMOBIIZATION AND BIOPSY DEVICE MR-BIOPSY MR BI 160
APPLICANT	MRI Devices Corporation
PRODUCT CODE	LNH
DECISION DATE	04/09/2001

Device Description:

The BI 160-O, BI 160-PA, and BI 160-CC device is a breast immobilization and biopsy accessory compatible with breast array coils and has the benefit of shaping the breast tissue into a "brick" shape, through mild compression. This allows for more efficient slice utilization. (i.e., fewer slices are needed to image the same amount of tissue).

The needle positioning devices allow the needle to be aimed at the lesion identified on the MR scan. Either MR compatible biopsy needles or MR compatible wire localization needles may be used.

510(k) Summary of Safety & Effectiveness

(as required by 21 CFR 807.92c)

Indications for Use:

The Breast Immobilization and Biopsy Device Models BI 160-O, BI 160-PA, and BI 160-CC are used in conjunction with a Magnetic Resonance Scanner to permit MR guided breast biopsy and wire localization of lesions that can be performed and interpreted by a trained physician.

Performance Data:

The BI 160-O, BI 160-PA, and BI 160-CC does not alter the performance of the coil in which it is placed.

No accuracy claims are made for the device. Slice warp in the MR image, needle deflection, and other factors will affect the accuracy of placing the needle into the breast lesion of interest. It is imperative that the clinician perform a scan with the needle in the breast to ensure that the needle has indeed entered the lesion of interest.

Conclusion:

The Breast Immobilization and Biopsy Device BI 160-O, BI 160-PA, and BI 160-CC is a modification of the MR BI 160 K010570.

Similar to the predicate device, the BI 160-O, BI 160-PA, and BI 160-CC does not control any life sustaining functions or services. The unmodified and modified device does not alter the performance of the MR coil in which it is placed.

Any differences between the predicate and subject devices will not affect safety or efficacy.

Based on the information supplied in this 510(k), we conclude that the subject device is safe, effective, and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2005

Noras Rontgen-Und Medizintechnik GMBH
% Carl Alletto
1600 Manchester Way
CORINTH TX 76210

Re.: K052987
Trade/Device Name: Breast Immobilization and Biopsy Device, Models BI 160-O, BI 160-PA and BI 160-CC
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Regulation Number: 21 CFR 892.1000
Regulatory Class: II
Product Code: MOS
Dated: October 10, 2005
Received: October 24, 2005

Dear Mr. Alletto:

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 (Premarket Approval), it may be subject to such 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.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

Indications for Use

510(k) Number (if known): K052987

Device Name:
Breast Immobilization and Biopsy Device Models BI 160-O, BI 160-PA, and BI 160-CC

Indications for Use:

The Breast Immobilization and Biopsy Device Models BI 160-O, BI 160-PA, and BI 160-CC are used in conjunction with a Magnetic Resonance Scanner to permit MR guided breast biopsy and wire localization of lesions that can be performed and interpreted by a trained physician.

Prescription Use __√√_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052987