K071534

JUL - 9 2007

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted as part of the PreMarket Notification in accordance with the requirements of 21 CFR Part 807, Subpart E and Section 807.92.

1. Identification of Submitter:

Submitter:	Confirma, Inc.
Address:	11040 Main Street, Suite 100 Bellevue, WA 98004
Phone:	425-691-1400
Fax:	425-691-1599
Contact:	Patricia A. Milbank, JD
Title:	Vice President, Regulatory Affairs/Quality Assurance
Phone:	425-894-9733
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Date Prepared:	May 29, 2007

2. Identification of Product:

Trade Name:	Confirma Breast MRI Interventional Components
Regulatory Number:	21 CFR 892.1000
Regulation Name:	Magnetic Resonance Diagnostic Device
Common Name:	System, Nuclear Magnetic Resonance Imaging
Regulatory Class:	Class II
Product Code:	90 MOS
Manufacturer:	Confirma, Inc. 11040 Main Street, Suite 100 Bellevue, WA 98004

3. Indications for Use

The Confirma Breast MRI Interventional Components are intended to be used in conjunction with a magnetic resonance scanner and the Confirma Access Breast Coil designs to permit MRI-guided interventional procedures, such as breast biopsy and localization of lesions that can be performed and interpreted by a trained physician.

4. Device Description:

The Confirma Breast MRI Interventional Components provide a grid system to immobilize the breast in an Access Breast Coil device. The grid system allows the physician to perform a biopsy through a needle block inserted in the grid plate. The system supports a standard medial-lateral approach using the Access Breast Coil.

The design of the interventional components focuses on ease of patient positioning and set-up by the clinician, and patient ergonomics for enhanced comfort during interventional procedures. The design allows for unilateral or bilateral access, and offers maximum access to aid the physician in MR-guided interventional procedures such as breast biopsy and localization of lesions, providing lateral and medial access to the breast. The components are provided non-sterile and are non-disposable. The components must be sterilized at the beginning of each procedure. The components are manufactured from Ultem 1000 polyetherimide which can be autoclaved or sterilized with formaldehyde.

The compression plate and grid plate system incorporate locking mechanisms that secure the components once positioned. These locks provide stability during the interventional procedure.

The compression and grid plates are bidirectional, allowing them to be placed in either a medial-facing or lateral-facing position. This allows the clinician to perform the interventional procedure from the medial or lateral side.

For unilateral breast intervention, the system uses one grid plate and one compression plate. For bilateral breast intervention, the system uses 2 grid plates and 2 compression plates.

The components are made of medical grade plastic materials, which are fire rated and have high impact and tensile strength.

Features of the Confirma Breast MRI Interventional Components:

- Optimized for parallel imaging applications
- Lateral and medial interventional access
- Supports both unilateral and bilateral imaging exams
- Compatible with Confirma Access breast coil designs
- 40 cm field of view
- Extensive coverage of chest wall and axilla
- Ergonomically designed for patient comfort to minimize motion artifact

5. Comparison with Legally Marketed Devices

The Interventional Components are substantially equivalent to the following legally marketed devices:

510(k) No.	Trade Name	Manufacturer	Product Code	Regulation Number
K001303	Breast Immobilization Device MR-BY 160	MRI Devices Corporation	90 MOS	892.1000
K020289	MICS Intervention Aid	Machnet BV	90 LNH	892.1000
K052704	Model BBD Breast Immobilization and Biopsy Device	Invivo Corporation	90 MOS	892.1000
K052987	Breast Immobilization and Biopsy Device, Models BI 160-0, BI 160-PA, and BI 160-CC	Noras Röntgen-und Medizintechnik GmbH	90 MOS	892.1000

The predicate devices are designed for use with MR scanners and standard breast coils to perform interventional breast procedures. The Confirma Breast MRI Interventional Components and the predicate devices allow bilateral and unilateral imaging and access of the breast as well as medial and lateral access to the breast for biopsy and interventional procedures.

6. Conclusions

The Confirma Breast MRI Interventional Components are substantially equivalent to the identified legally marketed devices. The potential hazards have been studied and controlled as part of the product development process, including risk analysis, test and design considerations, and planned verification and validation testing processes. The Confirma Breast MRI Interventional Components allow access and support for breast interventional procedures comparable to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL - 9 2007

Ms. Patricia A. Milbank
VP RA/QA
Confirma, Inc.
11040 Main Street, Suite 100
BELLEVUE WA 98004

Re: K071534
Trade/Device Name: Confirma Breast MRI Interventional Components
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: June 1, 2007
Received: June 5, 2007

Dear Ms. Milbank:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
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

Indication(s) for Use Statement

510(k) Number: To be assigned by FDA

Device Name: Confirma Breast MRI Interventional Components

Indications for Use:

The Confirma Breast MRI Interventional Components are intended to be used in conjunction with a magnetic resonance scanner and the Confirma Access Breast Coil designs to permit MRI-guided interventional procedures, such as breast biopsy and localization of lesions that can be performed and interpreted by a trained physician.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071534