K02 3686

JAN 2 9 2003

510(k) Summary
Aurora Imaging Technology, Inc.
Aurora® MR-Guided Interventional System

1. SPONSOR

Aurora Imaging Technology, Inc.
39 High Street
North Andover, MA 01845

Contact Person: Alan Oslan
Telephone: 987-975-7530, Ext. 4326

Date Prepared: October 31, 2002

2. DEVICE NAME

Proprietary Name:	Aurora® MR-Guided Interventional System
Common/Usual Name:	MR-Guided lesion localization system
Classification Name:	Accessory to a magnetic resonance device

3. PREDICATE DEVICES

- MRI Devices Breast Immobilization and Biopsy Device MR-Biopsy 160 (K010570)
- Philips Stereotactic Localization Device (K000832)

4. DEVICE DESCRIPTION

The use and operation of the Aurora® MR-Guided Interventional System and other MR-guided biopsy systems is based on the well-known method of target planning to determine the desired placement of an interventional device in three dimensions from an MR image. The basic targeting technique uses a three-dimensional MR-visible crosshair mounted near the needle guide in a fixed and known location. The stage is moved so that the needle guide and, consequently, the marker are moved to the general vicinity of the lesion to be targeted. The Aurora® MR-Guided Interventional System consists of four major subsystems: (1) Base plate system and components, (2) Needle guidance stage and components, (3) Position display unit (PDU), and (4) Target Planning Application (software).

5. INTENDED USE

The Aurora® MR-Guided Interventional System (the System) is an optional accessory to the Aurora Imaging Technology, Inc., Magnetic Resonance Diagnostic Device. The System is intended to aid in the performance of minimally invasive diagnostic procedures of the lateral or medial side of either breast and adjacent anatomies, which may be facilitated by MR guidance. Such procedures must be performed with MR-compatible devices as selected and evaluated by the clinical user.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Aurora® MR-Guided Interventional System is substantially equivalent to cited predicate devices in intended use, indications for use, design, and operation. The major difference between the Aurora® System and cited predicates is the ability to move the needle guidance stage in three directions.

7. PERFORMANCE TESTING

The Aurora® MR-Guided Interventional System was tested to and demonstrated in compliance with design and performance specifications and included biocompatibility testing, reprocessing validation, and verification/validation testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 9 2003

Mr. Alan Oslan
Program Manager, Interventional Systems
Aurora Imaging Technology
39 High Street
NORTH ANDOVER MA 01845

Re: K023686
Trade/Device Name: Aurora® MR-Guided Interventional System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: October 31, 2002
Received: November 1, 2002

Dear Mr. Oslan:

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.

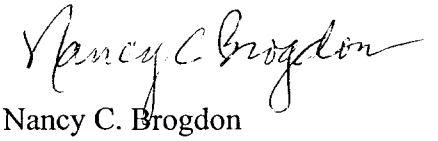
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K023686

Device Name: Aurora® MR-Guided Interventional System

Indications for Use:

The Aurora® MR-Guided Interventional System (the System) is an optional accessory to the Aurora Imaging Technology, Inc., Magnetic Resonance Diagnostic Device. The System is intended to aid in the performance of minimally invasive diagnostic procedures of the lateral or medial side of either breast and adjacent anatomies, which may be facilitated by MR guidance. Such procedures must be performed with MR-compatible devices as selected and evaluated by the clinician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lepore

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023686

Prescription Use √ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)