Spectroscopy Package for AURORA MRI System

SEP 1 6 2008

510 (k) Number: K073425

510(k) Summary for the

AURORA Magnetic Resonance Diagnostic Device

(Revised Version of "510(k) Summary" of the Original Submission)

510(k) Summary for the

AURORA Magnetic Resonance Diagnostic Device

(per 21 CFR 807.92)

1. Sponsor

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

Contact Person: J. P. Ouellette
Telephone: 978.975.7530 x4345

Date Prepared: September 12, 2008

2. Device Name

Proprietary Name: Aurora
Common/Usual Name: Magnetic Resonance Imaging Device
Classification Name: Magnetic Resonance Diagnostic Device

3. Predicate Device(s)

Aurora MRI System (K032082)
GE Probe (K930265)
Siemens (K951650)

4. Device Description

The modified AURORA is identical to the AURORA breast imaging system cleared by the FDA through K032082 except for the addition of the Spectroscopy pulse sequence protocol and its corresponding user interface software.

5. Intended Use

The AURORA MRI system is an imaging device, and is intended to provide the physician with physiological and clinical information obtained non-invasively and without the use of ionizing radiation. The MR system

produces transverse, coronal, and sagittal cross-sectional images that display the internal structure of breast tissue, axilla, and chest wall local to the breast. The images produced by the MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

The AURORA is a dedicated breast MRI system intended for breast imaging.

- Anatomical region: Breast tissue, axilla, and chest wall local to the breast
- Nucleus excited: Proton
- Diagnostic uses: 2D, 3D T1-/T2-weighted imaging
  T1, T2, proton density measurements
  Image processing
- Imaging Capabilities: 2D Spin Echo (SE)
  2D/3D Gradient Echo (GRE)
  Fat Suppression
- Imaging Processing: Image Subtraction
  Image Filtering

The Aurora MR Spectroscopy Package is intended for use as a non-invasive diagnostic device that provides information based on relative concentration of the Choline metabolite in breast tissues. The localized spectra reflect the NMR properties of proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and chemical shift. When interpreted by a trained medical practitioner, these spectral data provide information that can be useful in diagnosis determination.

6. Technological Characteristics and Substantial Equivalence

Aurora Imaging Technology, Inc., makes a claim of substantial equivalence of the modified AURORA to the predicate AURORA (K032082) based on similarities in intended use, design, and technological and operational characteristics. Both are indicated for magnetic resonance imaging of the breast. Both systems use the same hardware and software except that the modified device includes a new Spectroscopy Package.

7. Testing

Testing was performed to validate the safety and performance of the AURORA with the new pulse sequence.

Spectroscopy Package for AURORA MRI System

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Indications for Use Statement

(Revised Version of Section "Indications for Use Statement" of the Original Submission)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2008

J.P. Ouellette, M.S.
Director of Quality Assurance & Regulatory Affairs
Aurora Imaging Technology, Inc.
39 High Street
NORTH ANDOVER MA 01845

Re: K073425
Trade/Device Name: AURORA
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: August 25, 2008
Received: August 27, 2008

Dear Mr. Ouellette:

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 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). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K073425

Device Name: Spectroscopy Package for AURORA MRI System

Indications for Use: **AURORA**

The AURORA MRI system is an imaging device, and is intended to provide the physician with physiological and clinical information obtained non-invasively and without the use of ionizing radiation. The MR system produces transverse, coronal, and sagittal cross-sectional images that display the internal structure of breast tissue, axilla, and chest wall local to the breast. The images produced by the MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

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PRESCRIPTION USE ✓
(21 CFR 801 SUBPART D)

OVER-THE-COUNTER USE _____
(21 CFR 801 SUBPART C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K073425