K111251

Appendix A

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

MAY 27 2011

1. Classification and Device Name

Classification Name

Magnetic Resonance Diagnostic Device

Model Number

MJAJ-197A

Trade/Propriety Name

4ch Flex SPEEDER

2. Establishment Registration

2020563

3. U.S. Agent Name and Address

Agent Name

Toshiba America Medical Systems, Inc. (TAMS)
2441 Michelle Drive
Tustin, CA 92780

Contact Person

Paul Biggins, Director Regulatory Affairs
T: (714) 730-5000
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4. Manufacturing Site

Toshiba Medical Systems Corporation (TMSC)
1385, Shimoishigami, Otawara-Shi, Tochigi 324-8550, Japan

5. Date of Submission

May 3, 2011

6. Device Intended Use

Field Strength

1.5 T

Resonant Nucleus

Hydrogen

Anatomical Region of Interest

The extremities, joints, and trunk of the body.

Diagnostic Use

Diagnostic imaging of the human body, fluid visualization, 2D and 3D imaging, MR angiography, MR fluoroscopy and MRS

7. Device Description

The 4ch Flex SPEEDER is a phased array coil that can receive NMR signal from the extremities, joints, and trunk of the body. The 4ch Flex SPEEDER is mechanically flexible, and can wrap around various regions as mentioned above.

The 4ch Flex SPEEDER consists of four coil elements and PC board. The coil elements shape single loop and the four single loop coil elements are arranged to the row. The coil is decoupled during transmission from QD whole body by means of activating the PIN diodes.

8. Safety Parameter

Maximum static field strength

1.5 T

Maximum dB/dt

1st operation mode specified in IEC60601-2-33 (2002)

Maximum SAR

1st operation mode specified in IEC60601-2-33 (2002)

Peak and A-weighted Acoustic Noise Level

Not applicable

Biocompatibility

All materials used in contact with the patient have a history of use or test data that demonstrates its biocompatibility, i.e., non-toxic, non-irritating.

9. Imaging Performance Parameter

Sample phantom images and clinical images are presented in Appendix F & G of this submission.

10. Equivalency Information

Toshiba Medical Systems Corporation believes that this 4ch Flex SPEEDER is substantially equivalent to the current Atlas SPEEDER Body [K063361] and ϕ 200 flex coil [K060003].

11. Software

There is no software required for this coil.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Toshiba Medical Systems Corporation, Japan
% Mr. Paul Biggins
Director Regulatory Affairs/US Agent
Toshiba America Medical Systems, Inc.
2441 Michelle Dr
TUSTIN CA 92780

MAY 2 7 2011

Re: K111251
Trade/Device Name: 4ch Flex SPEEDER, MJAJ-197A
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: April 29, 2011
Received: May 4, 2011

Dear Mr. Biggins:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111251

Device Name: 4 ch.Flex SPEEDER, MJAJ-197A

Indications for Use:

1. Imaging of the extremities (Foot and Hand), joints (knee, shoulder, ankle, wrist and elbow), and body (chest, abdomen and pelvis)

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K111251

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