K121911

Appendix A

AUG 17 2012

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. Classification and Device Name

Classification Name

Magnetic Resonance Diagnostic Device

Model Number

MJAS-167A

Trade/Propriety Name

Octave SPEEDER Spine

2. Establishment Registration

2020563

3. Contact Person, U.S. Agent Name and Address

Contact Person

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U.S. Agent Name

Paul Biggins, Director, Regulatory Affairs
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Address:
Toshiba America Medical Systems, Inc. (TAMS)
2441 Michelle Drive
Tustin, CA 92780

4. Manufacturing Site

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

5. Date of Submission

June 28, 2012 (revised August 3, 2012)

6. Device Intended Use

Field Strength

1.5 T

Resonant Nucleus

Hydrogen

Anatomical Region of Interest

Spine

Diagnostic Use

Diagnostic imaging of the thoracolumbar spine.

7. Device Description

The Octave SPEEDER Spine is a receive-only phased Array Coil that can receive NMR signal from spine. The coil consists of a 12 rectangular loop surface coil. 3 loops (1 section) are aligned perpendicular to a body axis and 4 sections are aligned to a body axis. Users select the sections according to region of interest via a system user interface. The PC board switches transmit mode and receive mode with PIN diode. This coil is detuned during transmission by our QD whole body coil by means of activating the PIN diodes (transmit mode) and tuned during no transmission by means of not activating the PIN diodes (receive mode).

8. Indication for use

The Octave SPEEDER Spine is intended for imaging the thoracolumbar spine.

The MJAS-167A is intended to be used on a Toshiba 1.5T MR System

9. Design Change

The SPEEDER technology has been previously cleared under K063361 as an Atlas SPEEDER Spine coil. The primary difference is the creation of an 8ch SPEEDER Spine. The new Octave (8ch) SPEEDER Spine will use the same SPEEDER technology as other cleared SPEEDER devices.

10. 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 patient contacting materials have a history of use or test data that demonstrates its biocompatibility, i.e., non-toxic, non-irritating.

11. Summary of Testing

Testing was conducted utilizing phantoms and accepted imaging quality metrics.

12. Imaging Performance Parameter

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

13. Software

The Octave SPEEDER Spine coil does not contain software.

14. Equivalency Information

Toshiba Medical Systems Corporation believes that this Octave SPEEDER Spine is substantially equivalent to the current Atlas SPEEDER Spine [K063361]. Testing was done in accordance with applicable recognized consensus standards as listed below.

IEC60601-1 (1998), Amd1 (1991), Amd2 (1995)
IEC 60601-2 (2001), Amd1 (2004)
IEC60601-1-6 (2006)
IEC62366 (2007)
IEC60601-2-33 (2002), Amd1 (2005), Amd2 (2007)

15. Conclusion

The new Octave SPEEDER Spine (MJAS-167A) does not change the indication for use or the intended use of the predicate device. The safety and effectiveness has been verified via risk management and application of design controls to the new Octave SPEEDER Spine.

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

AUG 17 2012

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

Re: K121911
Trade/Device Name: Octave SPEEDER Spine, MJAS-167A
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: July 24, 2012
Received: July 26, 2012

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,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K121911

Indications for Use

510(k) Number (if known): **K121911**

Device Name: Octave SPEEDER Spine, MJAS-167A

Indications for Use:

The Octave SPEEDER Spine is intended for imaging the thoracolumbar spine.

The MJAS-167A is intended to be used on a Toshiba 1.5T MR System

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)

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

510(k) Number K121911