K073081
Page 1 of 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. Device Name	Magnetic Resonance Diagnostic Device Accessory
Model Name:	MRT-1503/S5, MRT-1503/S3
Trade/Proprietary Name	JET Software for EXCELART™ Vantage Atlas-Z, Atlas-X
2. Establishment Registration No.:	2020563
3. U.S Agent Name and Address:	Toshiba America Medical Systems, Inc.
	2441 Michelle Drive
	Tustin, CA 92780
Contact Person:	Paul Biggins
	(714) 730-5000
4. Manufacturing Site:	Toshiba Corporation
	Medical Systems Company
	1385 Shimoishigami
	Otawara-shi, Tochigi 32408550, Japan
5. Date of Submission:	October 26, 2007

NOV 21 2007

6. DEVICE DESCRIPTION

JET software provides high-resolution anatomical images with minimal artifacts due to physiological motion, which is caused by movement of anatomical regions due to breathing, CSF flow or other involuntary movements and can interfere with image quality.

6.1. Summary Of Major Hardware Changes

None

6.2. Summary Of Major Software Changes

Algorithm was modified to support a new combination of image acquisition and reconstruction techniques.

7. IMAGING PERFORMANCE PARAMETERS

No changes from the previously cleared K063361.

8. INTENDED USE

The intended use of the JET software is to get high-resolution anatomical images with minimal artifacts due to physiologic motion which can interfere with image quality. This technique can also provide the improvements on signal-to-noise with eliminating or reducing the image degradation caused by the motions. The software will be effective for any anatomies that can have the artifact caused by the physiologic motion such as below.

- CSF flow
- Abdominal or chest wall movement due to the breathing
- Respiratory movement on shoulders
- Uncontrolled movements due to the stroke, pediatric or uncooperative patients

9. EQUIVALENCY INFORMATION

Toshiba Medical Systems Corporation believes that the EXCELART Vantage Atlas-Z and Atlas-X (models MRT-1503/S5, MRT-1503/S3) Magnetic Resonance Imaging (MRI) System with JET software is substantially equivalent to the following:

- EXCELART Vantage Atlas-Z and Atlas-X (models MRT-1503/S5, MRT-1503/S3) cleared November 21, 2006 (K063361).

- "PROPELLER" manufactured by GE Medical Systems cleared May 2, 2003 (K031230), which uses a similar technique to reduce the motion-related artifact.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2007

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K073081
Trade/Device Name: JET Software for EXCELART Vantage Atlas-Z, EXCELART Vantage Atlas-X
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: October 31, 2007
Received: November 1, 2007

Dear Mr. Job:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(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 Biometric's (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,

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

Attachment 1

Indications for Use

510(k) Number (if known): K073081

Device Name: JET Software for EXCELART Vantage Atlas-Z, EXCELART Vantage Atlas-X

Indications for Use:

The intended use of the JET software is to get high-resolution anatomical images with minimal artifacts due to physiologic motion which can interfere with image quality. This technique can also provide the improvements on signal-to-noise with eliminating or reducing the image degradation caused by the motions.

Imaging of:

Any anatomies that can have the artifact caused by the physiologic motion such as:.

- CSF flow
- Abdominal or chest wall movement due to the breathing
- Respiratory movement on shoulders
- Uncontrolled movements due to the stroke, pediatric or uncooperative patients

Prescription Use ✓ OR Over-The-Counter Use_____
(Part 21 CFR 801Subpart D) (Part 21 CFR 801Subpart 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 K073081