K103629

FEB - 2 2011

510(k) Summary

Submitter's Name:	Toshiba America Medical Systems, Inc.
Address:	PO Box 2068, 2441 Michelle Drive Tustin, CA 92781-2068
Contact:	Paul Biggins, Director Regulatory Affairs
Telephone No.:	(714) 730-5000

Device Proprietary Name: Multiplane Transesophageal Transducer
Model PET-512MC

Common Name: Transesophageal Transducer

Classification:

- **Regulatory Class: II**
- **Review Category: Tier II**
- Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN
  [Fed. Reg. No.: 892.1550]
- Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO
  [Fed. Reg. No.: 892.1560]
- Diagnostic Ultrasonic Transducer – Product Code: 90-ITX
  [Fed. Reg. No.: 892.1570]

Identification of Predicate Devices:
Toshiba America Medical Systems believes that this device is substantially equivalent to:

- Toshiba APLIO XG Diagnostic Ultrasound System MODEL SSA-790A V4.0 R001, PET-510MB - 510(k) K092179
- Zonare Medical Systems Inc., z.one Ultra P8-3T - 510(k) K101091

Device Description:
The PET-512MC is a multiplane transesophageal transducer (TEE) designed for use with Toshiba Diagnostic Ultrasound Systems. It conforms to Track 3 when connected to the compatible ultrasound diagnostic systems. The scanning type of this transducer is a phased array with a frequency of 5MHz.

Indications for Use:
The PET 512MC is intended for visualization of the heart (and other organs) as a real-time ultrasound image. It is inserted into the esophagus through the mouth to visualize a plane of the heart through the esophageal wall.

Declaration of Conformity:
This transducer is designed and manufactured in conjunction with the Quality System Regulation, This device complies with IEC 60601-1 (applicable portions), IEC60601-2-37 (applicable portions), the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound Systems and the AIUM-NEMA UD3 Output Display Standard, when connected to diagnostic ultrasound systems.

Standards Form:
Please see the attached standard form of the IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-37 and IEC 62304.

Clinical Trials Form:
Please see the attached Clinical Trials Form FDA-3674

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Paul Biggins
Director, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

FEB - 2 2011

Re: K103629
Trade/Device Name: PET-512MC Transesophageal Transducer
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX, IYO, and IYN
Dated: December 8, 2010
Received: December 13, 2010

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the PET-512MC Transesophageal Transducer, as described in your premarket notification:

Transducer Model Number

PET-512MC

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 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 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 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 market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

If you have any questions regarding the content of this letter, please contact Paul Hardy at (301) 796-6542.

Sincerely Yours,

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

Enclosure(s)

INDICATIONS FOR USE

510(K) Number (if known): _____

Device Name: PET-512MC Transesophageal Transducer

Indications for Use:

The PET 512MC is a multiplane transesophageal transducer (TEE) designed for use with Toshiba Diagnostic Ultrasound Systems for the visualization of the heart (and other organs) as a real-time ultrasound image. It is inserted into the esophagus through the mouth to visualize a plane of the heart through the esophageal wall.

Prescription Use_____ 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

510K K103629

System: Aplio Artida v2.7 SSH-880CV
Transducer: PET-512MC

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation											
Specific (Tracks 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	3D	Other [Note]
Ophthalmic												
Fetal												
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic												
Pediatric												
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												
Trans-rectal												
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	P	P	P	P	P	3	P					4
Intra-cardiac												
Other (Specify)												
Peripheral vessel												
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix
Previous 510(k) of the transducer: K090158

Note 1 Small organ includes thyroid, breast and testicle.
Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
Note 4 TDI
Note 5 ApliPure
Note 6 MicroPure
Note 7 Precision Imaging
Note 8 STIC
Note 9 3D color
Note 10 STIC Color
Note 11 Elastography (New)

Prescription Use Only (Per 21 CRF801.109)

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

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