NOV 17 2004

K043078

510(k) Summary of Safety and Effectiveness: 21 CFR 807.92

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

Device Proprietary Name: NEMIO, SSA-550A
Common Name: Ultrasound Imaging System

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 the Following devices:

1) Toshiba NEMIO SSA-550A Diagnostic Ultrasound System, 510(k) control number K010631
2) Siemens G60 Diagnostic Ultrasound System, 510(k) control number K040060

Device Description:

The NEMIO will be offered in three variations all of which are mobile systems. These systems are all Track 3 devices that employ a wide array of probes that include flat linear array, convex linear array, and sector array with a frequency range of approximately 2 MHz to 12 MHz. The differences in systems will be the availability of various options such as size of monitor, ultrasonic, modes, and post processing display capabilities.

Intended Use:

The NEMIO systems are intended to be used for the following type of studies; fetal, abdominal, intraoperative, pediatric, small organs, neonatal cephalic, adult cephalic, cardiac, transrectal, transvaginal, transesophageal, peripheral vascular, musculo-skeletal (both conventional and superficial), and laparoscopic.

Safety Considerations:

These devices are designed and manufactured in conjunction with the Quality System Regulation, IEC 60601-1, IEC 60601-1-2(2001), IEC 60601-2-37(2001), IEC 60601-2-37 Amd.1(2004) and the AIUM-NEMA UD2 Output Measurement Standard as applied to the Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2004

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
2441 Michelle Drive
TUSTIN CA 92780

Re: K043078
Trade Name: NEMIO Diagnostic Ultrasound System, Model SSA-550A
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: November 3, 2004
Received: November 8, 2004

Dear Mr. Job:

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 NEMIO Diagnostic Ultrasound System, Model SSA-550A, as described in your premarket notification:

Transducer Model Number

PVM-375MV

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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications For Use Form

System _X_ Transducer___
Model___NEMIO; SSA-550A
510(k) Number(s) _____

Clinical Application	A	Mode of Operation								
		B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P	P	P	P
Abdominal		P	P	P	P	P	P	P	P	P
Intraoperative (small organs)		P	P	P		P	P	P	P	
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P	P	P	P
Small Organ (Specify)		P	P	P		P	P	P	P	P
Neonatal Cephalic		P	P	P	P	P	P	P	P	P
Adult Cephalic		P	P	P	P	P	P	P	P	P
Cardiac		P	P	P	P	P	P	P	P	P
Transesophageal		P	P	P	P	P	P	P	P	P
Transrectal		P	P	P		P	P	P	P	
Transvaginal		P	P	P		P	P	P	P	P
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P	P	P	P	P	P	P
Laparoscopic		P	P	P		P	P	P	P	P
Musculo-skeletal Superficial		P	P	P		P	P	P	P	P
Musculo-skeletal Conventional		P	P	P		P	P	P	P	P
Endoscopic										
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; B-TDI; M-TDI

Previous 510(k) control Number: k010361

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043078

NEW TRANSDUCER TABLE

Transducer Model Number: PVM-375MV

510(k) Control Number:

Clinical Application	A	Mode of Operation: B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging
Ophthalmic										
Fetal		N	N	N		N	N	N	N	N
Abdominal		N	N	N		N	N	N	N	N
Intraoperative										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N	N
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Superficial										
Musculo-skeletal Conventional										
Other (specify)										

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; B-TDI; M-TDI

This is a new transducer but all indications have been previously cleared on existing transducers.

(OCRAE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER FACES IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (per 21 CFR 801 109)

David A. Legassa

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K043078