Chapter 4. 510(k) Summary

Submitter's Name:	Panasonic Healthcare Co., Ltd.
Address:	Medical Imaging Business Unit 600 Saedo-Cho, Tsuzuki-Ku Yokohama, 224-8539 Japan
Contact:	Keijiro Asayama, Division Director
Telephone:	+81 45 939 1010
Date:	December 5, 2011
Trade Name:	AIDA V1.5 Diagnostic Ultrasound System GM-72P00A
Model No:	GM-72P00A
Common Name:	Ultrasound Imaging System
Classification Name(s):	Ultrasonic Pulsed Doppler Imaging System (21 CFR 892.1550) Ultrasonic Pulsed Echo Imaging System (21 CFR 892.1560) Diagnostic Ultrasound Transducer (21 CFR 892.1570)
Classification Number(s):	90-IYN; 90-IYO; 90-ITX
Regulatory Class:	Class II
Predicate Device(s):	K103148 – AIDA Diagnostic Ultrasound System GM-72P00A, Panasonic Healthcare Co., Ltd K093171 – Viamo SSA-640A, Toshiba America Medical Systems, Inc.

Device Description:

The AIDA V1.5 Diagnostic Ultrasound System GM-72P00A is a portable ultrasound system optimized to perform a non-invasive examination of the peripheral vessels. It provides an automated measurement of the intima-media thickness (IMT) of peripheral arteries such as the common carotids and allows the user to search for arterial plaques using real-time Brightness and Color Doppler imaging modes. The touchscreen

keyboard allows the user to input various parameters relating to traditional cardiovascular risk factors. A built in calculator provides risk scores commonly used in a variety of geographical locations (Framingham Risk Score, PROCAM Health Check Score, Reynolds Risk Score, Risk score based on the SCORE Project). This information is supplemented with an IMT measurement of the artery to generate a comprehensive report of cardiovascular risk assessment.

The AIDA V1.5 Diagnostic Ultrasound System GM-72P00A is designed to comply with the following standards:

UL 60601-1: 2003;
IEC 60601-1-1: 2000;
IEC 60601-1-2: 2nd Edition (2001), Amendment 1 (2004);
IEC 60601-2-37: 2001, Amendment 1 (2004), Amendment 2 (2005);
IEC 62304: Ed. 1.0 (2006);
ISO 10993-1:2009; ISO 10993-5:2009; ISO 10993-10:2010;
NEMA UD 2-2004; NEMA UD 3-2004;

Intended Use:

The AIDA V1.5 Diagnostic Ultrasound System GM-72P00A is intended for Peripheral Vessel applications. The system provides an automated intima-media thickness measurement of peripheral vessels such as the common carotid in the BIMT-mode of operation for heart rate range of 20-150 beats per minute.
The AIDA V1.5 Diagnostic Ultrasound System GM-72P00A is contraindicated for fetal use.

Technological Comparison to Predicate Device

The AIDA V1.5 Diagnostic Ultrasound System GM-72P00A is substantially equivalent to products that have already been cleared for USA distribution with 510(k) premarket notification numbers K103148 and K093171. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures. All systems permit specialized measurement of anatomic structures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

FEB 10 2012

Panasonic Healthcare Co., Ltd.
% Mr. Ram Bedi
President
Puget Ultrasound, Inc.
2425 Squak Mountain Loop SW
ISSAQUAH WA 98027

Re: K113612
Trade/Device Name: AIDA V1.5 Diagnostic Ultrasound System GM-72P00A
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: December 5, 2011
Received: December 6, 2011

Dear Mr. Bedi:

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 AIDA V1.5 Diagnostic Ultrasound System GM-72P00A, as described in your premarket notification:

Transducer Model Number

LV13-5V1

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 Lauren Hefner at (301) 796-6881.

Sincerely Yours,

for

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(s)

Indications for Use Statement

510(k) Number: K113612

Device Number: AIDA V1.5 Diagnostic Ultrasound System GM-72P00A

Company Name: Panasonic Healthcare Co., Ltd.

Indications for Use:

The AIDA V1.5 Diagnostic Ultrasound System GM-72P00A is intended for Peripheral Vessel applications. The system provides an automated intima-media thickness measurement of peripheral vessels such as the common carotid in the BIMT-mode of operation for heart rate range of 20-150 beats per minute. The AIDA V1.5 Diagnostic Ultrasound System GM-72P00A is contraindicated for fetal use.

Prescription Use ____X_____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Per 21 CFR 801 Subpart 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 Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113612

System: **AIDA V1.5 Diagnostic Ultrasound System GM-72P00A**
Transducer: _____

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P				N	1	
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: Combined mode BIMT (B + IMT)

Prescription Use Only (Per 21 CFR801.109)

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

510K K113612

System: **AIDA V1.5 Diagnostic Ultrasound System GM-72P00A**
Transducer: **LV13-5V1**

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P				N	1	
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: Combined mode BIMT (B + IMT)

Prescription Use Only (Per 21 CFR801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K113612