10/22/99 Revised Version forthcoming per 10/22/99 teleconference request.

NOV - 1 1999

SIUI

SHANTOU INSTITUTE OF ULTRASONIC INSTRUMENTS
汕头超声仪器研究所

K984203

Premarket Notification [510(k)] Summary

August 10, 1999 (revised)

Trade Name: SIUI Apogee 800 PLUS Ultrasound Imaging System
SIUI 5-2 C40 Transducer
SIUI 11-5L40 Transduced

Common Name: Ultrasound Imaging System

Classification: This product is substantially equivalent to one or more of the products FDA has classified or has proposed classification, as Class II devices, including

Ultrasonic pulsed Doppler imaging system	21 CFR 892.1550
Ultrasonic pulsed echo imaging system	21 CFR 892.1560
Diagnostic ultrasonic transducer	21 CFR 892.1570

Manufacturer's Name: Shantou Institute of Ultrasonic Instruments
Address: #2, Jinsha Road, M.,
Shantou Sez, 515041, China

Corresponding Official: Mr. Jinzhong Yao
Title: President

Telephone: (86) 754-8250150 Fax: (86) 754-8251499

Establishment Registration Number: 9615439

Predicate: Advanced Technology Laboratories, Ultramark 9 HDI system, K903603 and Interspec Inc Apogee RX 400, K924231

Device Description: Apogee 800 PLUS transmits ultrasound waves, receives the echoes, and generates images based on information contained in the echoes.

The format in which the information is displayed depends on the imaging mode or modes that you select. The system is capable of

real-time two-dimensional (2D) imaging, motion mode (M-mode) imaging, Doppler imaging, Power imaging, and color imaging.

The system supports application and exam type presets, which means that the system is automatically optimized for the scanhead and application you have selected. Additionally, analysis protocols are made available so that you can store measurements in the patient's report.

Physically the system consists of the monitor module, the control module, the main chassis, and transducers.

Intended Use: Ultrasonic pulsed echo imaging, measurement, color Doppler, and color velocity imaging for Fetal, Abdominal, Pediatric, Small Organ, and Peripheral Vascular.

Technological Characteristics: See the attached four Comparison Tables for the SIUI Apogee 800 PLUS and the ATL Ultramark 9.

SIUI Apogee 800PLUS Ultrasound Imaging System

1 Indications for Use

Device Type	Ophthalmic	Fetal	Abdominal	Pediatric	Small Organ	Cardiac	Peripheral Vascular
ATL Ultramark 9	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SIUI Apogee 800PLUS	No	Yes	Yes	Yes	Yes	No	Yes

2 OPERATION MODES

Device Type	2-D B	M	PW	CW	Color Flow	HPRF	CPA	Color M
ATL Ultramark 9	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
SIUI Apogee 800PLUS	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes

3 DISPLAY FORMATS

DISPLAY FORMATS		SIUI Apogee 800PLUS	ATL Ultramark 9
Full Screen	2 D B-MODE	Yes	Yes
	M-MODE	Yes	Yes
	CFM	Yes	Yes
	COLOR M-MODE	Yes	Yes
	DOPPLER SPECTRUM	Yes	Yes
Top/Bottom Split Screen	2D/DOPPLER SPECTRUM	Yes	Yes
	2D/M	Yes	Yes
	CFM/DOPPLER SPECTRUM	Yes	Yes
	CFM/M	Yes	Yes
	CFM/COLOR M	Yes	Yes
Side by Side Split Screen	2D/2D	Yes	Yes
	2D/CFM	Yes	Yes
	CFM/CFM	Yes	Yes
	CFM/CPA	Yes	No
	2D/2D ZOOM	Yes	Yes
	CFM/COLOR ZOOM	Yes	Yes
General Formats	Freeze Frame	Yes	Yes
	Apex Invert	Yes	Yes
	Left/Right Reverse	Yes	Yes
	Video Invert for Doppler Spectrum	Yes	Yes
	Video Invert for M-Mode	Yes	Yes

*** CFM – COLOR FLOW IMAGING or COLOR DOPPLER**

4 Other Specifications

	ATL Ultramark 9	**SIUI Apogee 800PLUS**
Gray Scale	256 (8bits)	256 (8 bits)
Frame Rate (Max)	156 FPS	70 FPS
Beamformer	Digital	Analog
Signal post processing	Yes	Yes
Image Modification	8x, continuously variable	24x, continuously variable
Preprogrammability	Yes	Yes
Cineloop	Yes	Yes
Imaging depth (max)	25 (cm)	24 (cm)
Doppler measurable velocities (max)	13.6 m/s (for CW)	8 m/s (for PW)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 1999

Shantou Institute of Ultrasonic Instruments
c/o Robert Morton
President
QRS
1106 Chiltern Drive
Walnut Creek, CA 94596

Re: K984203
SIUI Apogee 800PLUS Ultrasound Imaging System
Regulatory Class: II
21 CFR 892.1550/Procode: 90 IYN
Dated: August 9, 1999
Received: August 17, 1999

Dear Mr. Morton:

We have reviewed your Section 510(k) 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 SIUI Apogee 800PLUS Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

Convex Array 5-2C40
Linear Array 11-5L40

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Re: K984203

SIUI Apogee 800PLUS Ultrasound Imaging System

Indications for Use Form

Diagnostic Ultrasound System Indications for Use Form

Device Name: SIUI Apogee 800 PLUS

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

N=new indication

Additional Comments: Small organ includes: thyroid, parathyroid, submaxillary gland, testes and breast

Combined Modes: Fetal: B+M

Abdominal: B+M

Pediatric: B + M, B + PWD, B + Color, B + Color + M, B + Color + PWD

Small Organ: B + M, B+PWD, B + Color, B +Color +M, B+ Color + PWD

Peripheral Vascular: B+M, B+ PWD, B+ color, B + Color + M, B + Color + PWD

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K984203

Re: K984203

SIUI Apogee 800PLUS Ultrasound Imaging System

1. Scanhead Indications for Use Form

Device Name: Convex Array 5-2 C 40

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

N=new indication

Additional Comments: Small organ includes: thyroid, parathyroid, submaxillary gland, testes and breast

Combined Modes: Fetal: B+M, Abdominal: B+M,

Pediatric: B + M, Small Organ: B + M,

Peripheral Vascular: B+M,

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Concurrence of CDRH, office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K984203

Re: K984203

SIUI Apogee 800PLUS Ultrasound Imaging System

2. Scanhead Indications for Use Form
Device Name: Linear Array 11-5 L 40

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

N=new indication

Additional Comments: Small organ includes: thyroid, parathyroid, submaxillary gland, testes and breast

Combined Modes: Pediatric: B + M, B + PWD, B + Color, B + Color + M, B + Color + PWD

Small Organ: B + M, B+PWD, B + Color, B +Color +M, B + Color + PWD

Peripheral Vascular: B+M, B+ PWD, B+ color, B + Color + M, B + Color + PWD

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Prescription Use (Per 21 CFR 801.109)

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