

MAY 5 1999

Tab 11**Premarket Notification [510(k)] Summary**

September 7, 1998

Trade Name: CTS-310B with EZU-PL12 and EZU-PC3A Transducers**Common Name:** Diagnostic Ultrasound System**Classification Name:** Ultrasonic Pulsed Echo Imaging System, 90 IYO
(per 21 CFR section 892.1560)**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**Predicate:** Hitachi Medical Corporation EUB-310, K862867

Device Description: Model CTS-310B is a linear/convex electronic scanning ultrasonotomograph with a built-in digital scan converter (DSC). The unit allows heart, abdominal organic and fetal tomographic images to be observable on a video monitor. The main unit is portable and is separable from other equipment to be carried for its use at another place as well as being usable in combination with a 9-inch video monitor and a special photographic unit.

Intended Use: Ultrasonic pulsed echo imaging and measurement for fetal imaging and other abdominal as well as pediatric, small organ, neonatal cephalic, adult cephalic, and heart.

Technological Characteristics: See the attached "Comparison List" of the SIUI CTS-310B and the Hitachi EUB-310.

COMPARIS ON LIST OF SIUI PRODUCT AND HITACHI PRODUCT

Performance		CTS-310 (SIUI)	EUB-310A (HITACHI)
main unit	scanning mode	electronic linear scanning (compatible 80 elements linear probe) electronic convex sector (compatible convex probe of 80 elements)	electronic linear scanning (compatible 80 elements linear probe) electronic convex sector (compatible convex probe of 80 elements)
	display mode	B mode B/B ode, M mode, B/M mode simultaneously	B mode, B/B mode, M mode, B/M mode simultaneously
	measure-ment	in B mode display: distance, area and circumference in M mode display: time interval, velocity, depth and heart rate	in B mode display: distance, area and circumference in M mode display: time interval, velocity, depth and heart rate
	calculation	area, circumference, volume, heart rate, pregnant weeks and heart function	area, circumference, volume, heart rate, pregnant weeks and heart function
	focusing mode	4-steps dynamic focusing with variable aperture and lens focusing	4-steps dynamic focusing with variable aperture and lens focusing
	scanning width	linear scanning: 3.5MHz probe 104mm, 5MHz probe 61mm convex sector scanning probe: sector angle 60°	linear scanning: 3.5MHz probe 104mm, 5MHz probe 61mm convex sector scanning probe: sector angle 60°
	transmitting voltage	pulse height 130V	pulse height 130V
	transmitting pulse width	3.5MHz pulse width 140 μs 5MHz pulse width 100 μs	3.5MHz pulse width 140 μs 5MHz pulse width 100 μs
	detecting depth	3.5MHz probe maximum depth: 210mm 5MHz probe maximum depth: 140mm	3.5MHz probe maximum depth: 210mm 5MHz probe maximum depth: 140mm
	zoom	3.5MHz probe: x1.0, x1.2, x1.5, x2.0 selectable as well as depth shift 5MHz probe: x1.0, x1.5, x2.0 selectable as well as depth shift	3.5MHz probe: x1.0, x1.2, x1.5, x2.0 selectable as well as depth shift 5MHz probe: x1.0, x1.5, x2.0 selectable as well as depth shift
	frame rate	the maximum is 40 frame / second	the maximum is 40 frame / second
	grey scale	16	16
	memory	512 x 512 x 4 bit	512 x 512 x 4 bit
	coordinate transformation function	monitor can display electronic linear scanning image or convex sector scanning image	monitor can display electronic linear scanning image or convex sector scanning image

COMPARIS ON LIST OF SIUI PRODUCT AND HITACHI PRODUCT

Performance		CTS-310 (SIUI)	EUB-310A (HITACHI)
main unit	video output	PAL or NTSC system TV signal (confirmed in order)	PAL or NTSC system TV signal (confirmed in order)
	power supply	100V, 110V, 117V, 200V, 220V or 234V, $\pm 10\%$, 50/60Hz, about 250W	100V, 110V, 117V, 200V, 220V or 234V, $\pm 10\%$, 50/60Hz, about 250W
	monitor	9" black and white monitor	5.5" and 9" black and white monitor
	volume and weight	395 (W) x 1180 (H) x 728 (L)mm approx. 65 kg	405(w) X 710(1) X 1310(h)mm approx. 40kg
	cursor shift	by trackball on keyboard	by joystick on keyboard
	electric apparatus safty standard	conform to requirement of I class B type apparatus of IEC 601-1 isolate resistor testing: testing voltage 1000V L-L, L-G \geq 10MG leakage current: U*-G \leq 500 μ A P-G \leq 100 μ A voltage resistance testing: L-G, P-G 1500V 2mA, no sparking or arcing in 1 minute work normally when voltage changes $\pm 10\%$	conform to requirement of I class B type apparatus of IEC 601-1 isolate resistor testing: testing voltage 1000V L-L, L-G \geq 10M Ω leakage current: U*-G \leq 500 μ A P-G \leq 100 μ A voltage resistance testing: L-G, P-G 1500V 2mB, no sparking or arcing in 1 minute work normally when voltage changes $\pm 10\%$
probe ultrasound transmitting frequency	linear probe: EZU-PL12 80 elements, 5MHz scanning width 61mm EZU-PC3A 80 elements, 40R, 3.5MHz scanning angle 60°	linear probe: EZU-PL11 80 elements, 3.5MHz scanning width 104mm EZU-PL12 80 elements, 5MHz scanning width 61mm Euu-L11S 80 elements, 3.5MHz scanning width 84mm convex sector probe: EZU-PC3A 80 elements, 40R, 3.5MHz, scanning angle 60° EZU-PC2A 80 elements, 40R, 5MHz, scanning angle 60° EUP-V12A 40 elements, 40R, 5MHz, scanning angle 40° (transvaginal probe)	
operation environment	temperature 5-40°C, relative humidity 30-85% (no water drop)	temperature 5-40 °C, relative humidity 30-85% (no water drop)	
storage environment	temperature -10-60°C, relative humidity 30-95% (no water drop) air pressure 700-1060mB	temperature -10-60°C, relative humidity 30-95% (no water drip) air pressure 700-1060mB	
note			

*U means main unit.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Shantou Institute of Ultrasonic Instruments
C/O Robert J. Morton, M.S.
President & Certified Radiological Physicist
Quality & Regulatory Services
1106 Chiltern Drive
Walnut Creek, California 94596

Re: K984161
SIUI CTS-310B Ultrasound Imaging System
Dated: April 1, 1999
Received: April 5, 1999
Regulatory Class: II
21 CFR 892.1560/Procode: 90 IYO

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 CTS-310B Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

EZU-PL12
EZU-PC3A

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 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:

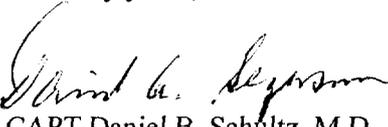
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 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 Perez at (301) 594-1212.

Sincerely yours,

for 
CAPT Daniel B. Schultz, M.D.
Acting Director
Division of Reproductive,
Abdominal, Ear, Nose and Throat,
And Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Devices

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form
Device Name: SIUI CTS-310B

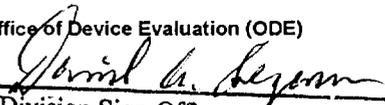
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	C (s)
Ophthalmic										
Fetal		N	N						N	
Abdominal		N								
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N						N	
Small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

N=new indication

Additional Comments: thyroid gland, breast, testes

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, ENT,
 and Radiological Devices
 510(k) Number K984161

Prescription Use (Per 21 CFR 801.109)

Scanhead Indications for Use Form
Device Name: EZU-PL12

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							
Abdominal		N								
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N								
Small Organ (specify)		N								
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal superficial										
Other (specify)										

N = new indication

Additional Comments: thyroid gland, breast, testes

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Concurrence of CDRH, office of Device Evaluation (ODE)

David A. Ferguson
 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

510(k) Number K984161

Prescription Use (Per 21 CFR 801.109)

Scanhead Indications for Use Form
Device Name: EZU-PC3A

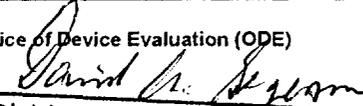
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N						N	
Abdominal		N								
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N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

N = new indication

Additional Comments: _____

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