K963065

SIUI

SHANTOU INSTITUTE OF ULTRASONIC INSTRUMENTS

MAY 29 1997

Premarket Notification [510(k)] Summary

July 30, 1996 (Revised 5/6/97)

Trade Name: CTS-285 with EZU-PL21 and EZU-PC3B 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-285 is a compact-type linear/convex electronic scanning ultrasound system with a built-in digital scan converter (DSC). The unit allows adult heart, abdominal organ 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 full keyboard, 9-inch video monitor and a special photographic unit.

Intended Use: Ultrasonic pulsed echo imaging and measurement for fetal, abdominal, and adult cardiac imaging as well as adult cardiac M-mode.

Technological Characteristics: See the attached "Comparison List" of the SIUI CTS-285 and the Hitachi EUB-310.

ADD: JINSHA ROAD M., SHANTOU, CHINA POSTCODE: 515041

COMPARISON LIST OF SIUI PRODUCT AND HITACHI PRODUCT

Performance		CTS-285 (portable) (SIUI)	EUB-310A (HITACHI)
main unit	scanning mode	electronic linear scanning (compatible 64 elements linear probe) electronic convex sector (compatible convex probe of 64 elements)	electronic linear scanning (compatible 80 elements linear probe) electronic convex sector (compatible convex probe of 80 elements
	display mode	B mode, B/B mode, M mode, B/M mode simutaneously	B mode, B/B mode, M mode, B/M mode simutaneously
	measurement	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 102mm, 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 160μs	3.5MHz pulse width 140μs 5MHz pulse width 100μs
	detecting depth	3.5MHz probe maximum depth: 210mm	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	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 maxium is 40 frame/second	the maximum is 40 frame/second
	grey scale	16	16
	memory	512x512x4 bit	512x512x4 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

COMPARISON LIST OF SIUI PRODUCT AND HITACHI PRODUCT

Performance		CTS-285 (portable) (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, ±10%, 50/60Hz, about 140W	100V, 110V, 117V, 200V, 220V or 234V, ±10%, 50/60Hz, about 250W
	monitor	5.5" black and white monitor	5.5" and 8" black and white monitor
	volume and weight	280(W)x235(H)x415(L)mm approx. 13kg	405(w)x710(l)x1310(h)mm approx. 40kg
	cursor shift	by trackball on keyboard	by joystick on keyboard
	electric apparatus safty standard	conform ot requirement of I class B type apparatus of IEC 601-1 isolate resistor testing: testing voltage 1000V L-L, L-G≥10MG leakage current: U~-G≤500μA P-G≤100μA voltage resistance testing: L-G, P-G 1500V 2mA, no sparking or arcing in 1 minute work normally when voltage changes ±10%	conform to requirement of I class B type apparatus of IEC 601-1 isolate resistor testing: testing voltage 1000V L-L, L-G≥10MΩ leakage current: U~-G≤500μA P-G≤100μA voltage resistance testing: L-G, P-G, 1500V 2mA, no sparking or arcing in 1 minute work normally when voltage changes ±10%
probe ultrasound transmitting frequency		linear probe: EZU-PL21 64 elements, 3.5MHz, scanning width 102mm Convex sector probe: EZU-PC3B 64 elements, 40R, 3.5MHz, scanning width 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° (transverginal probe)
operation environment		temperature 5-40° C, relative humidity 30-50% (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 drop) air pressure 700-1060mB
note			

* U means main unit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Shantou Institute of Ultrasonic Instruments
c/o Robert J. Morton, President
Quality and Regulatory Services
1106 Chiltern Drive
Walnut Creek, CA 94596

MAY 29 1997

Re: K963065
CTS-285 Diagnostic Ultrasound
System with Model EZU-PL21
and EZU-PC3B Transducers
Dated: April 4, 1997
Received: April 7, 1997
Regulatory Class: II
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.1570/Procode: 90 ITX

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 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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the CTS-285 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

EZU-PL21 (3.5MHz)
EZU-PC3B (3.5MHz)

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 for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 "dsmo@fdadr.cdrh.fda.gov".

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

Sincerely yours,

for Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K963065
Device Name: Transducer 3.5 MHz EZU-PL21 for CTS-285

Fill out one form for each ultrasound system or transducer.

Indications For Use: Diagnostic ultrasound imaging ~~or Doppler analysis~~ (Specify) of the human body as follows:

Clinical Application	Mode of Operation: A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		X								
Abdominal		X								
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult			X							
Cardiac Pediatric										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Intra-luminal										
Trans-urethral										
Peripheral vessel										
Laparoscopic										

Other Indications or Modes: _____

(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

Prescription Use (Per 21 CFR 801.109)

510(k) Number K963065

510(k) Number (if known): K963065
Device Name: Transducer Model 3.5MHz EZU-PC3B for CTS-285

Fill out one form for each ultrasound system or transducer.

Indications For Use: Diagnostic ultrasound imaging [redacted] (Specify) of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		X								
Abdominal		X								
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac Adult		X	X							
Cardiac Pediatric										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Intra-luminal										
Trans-urethral										
Peripheral vessel										
Laparoscopic										

Other Indications or Modes: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K963065

Prescription Use (Per 21 CFR 801.109)