K033604

DEC 15 2003

510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Colleen Densmore, Official Correspondent
8000 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
Facsimile: (317) 5779070

Contact Person: Colleen Densmore

Date: November 11, 2003

807.92(a)(2)

Trade Name:	50L Tringa Ultrasound Imaging System	
Common Name:	Ultrasound Imaging System	
Classification Name(s):	Ultrasonic pulsed echo imaging system	892.1560
Classification Number:	90IYO	

807.92(a)(3)

Predicate Device(s)

Pie Medical	50S Tringa	K020112
SonoSite	i Look 25	K021628

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

807.92(a)(4) **Device Description**

The 50L Tringa ultrasound system is a lightweight, low-output, portable, real-time, ultrasound scanner used to acquire and display images in 2D, M or a combination of these modes. The 50L Tringa system has one linear probe and can be operated via rechargeable battery and/or mains connection.

807.92(a)(5) **Intended Use(s)**

Pie Medical's 50L Tringa ultrasound system is to be used by or under the direction of a physician to perform general non-invasive and invasive diagnostic ultrasound imaging studies, to include: abdominal, neonatal cephalic, pediatric, peripheral vascular, small organs, intraoperative abdominal, intraoperative vascular and musculoskeletal (conventional and superficial). The system provides ultrasound guidance for freehand or biopsy guided placement of needles and catheters in vascular or other anatomical structures.

Comparison Chart for Substantial Equivalence

General characteristics	Pie Medical 50L Tringa This Submission	Pie Medical 50S Tringa K020112	Sonosite iLook 25 K021628
Intended Use			
Pediatric	Yes	No	Yes
Small Organs	Yes	Yes	Yes
Intraoperative (abdominal and vascular)	Yes	No	Yes
Peripheral Vascular	Yes	Yes	Yes
Musculoskeletal (Conventional & Superficial)	Yes	No	Yes
Abdominal	Yes	Yes	Yes
Neonatal Cephalic	Yes	No	Yes
Transducer Type			
Linear	Yes	No	Yes
2D Freq MHz	10 - 5	3.5/5.0/7.5	10 - 5
Biopsy Guidance	Yes	No	Yes
Free-Hand Vascular Access	Yes	No	Yes
Display Type	LCD	LCD	LCD
Imaging Modes	2D / M-mode	2D / M-mode	2D – Color Doppler
Monitor Size	5 inch	5 inch	5 inch
Digital Archival capabilities	Yes	Yes	Yes
VCR	Yes	Yes	Yes
Safety			
Electrical Safety	EN60601-1	EN60601-1	EN60601-1
Ultrasound Safety	Track 1	Track 1	Track 3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2003

Pie Medical
% Ms. Colleen Densmore
Official Correspondent
The Anson Group
7992 Castleway Drive
INDIANAPOLIS IN 46250

Re: K033604
Trade Name: 50L Tringa Ultrasound 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 IYO and ITX
Dated: November 11, 2003
Received: November 17, 2003

Dear Ms. Densmore:

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 50L Tringa Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

LA/7.5 MHz/L20/64el

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 (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 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,

David A. Lyerman

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

50L Tringa Ultrasound Imaging System

Clinical application	Mode of Operation								
	A	B	M	PWD	Color Doppler	Ampl. Doppler	Color Velocity Imaging	Combined	Other
Ophthalmic									
Fetal									
Abdominal		N	N					(2)	(1)
Pediatric		N	N					(2)	(1)
Small organs		N	N					(2)	(1)
Neonatal cephalic		N	N					(2)	(1)
Cardiac									
Cardiac Pediatric									
Transesophageal									
Transrectal									
Transvaginal									
Transurethral									
Intra-operative (abdominal)		N	N					(2)	(1)
Intra-operative (vascular)		N	N					(2)	(1)
Peripheral vascular		N	N					(2)	(1)
Laparoscopic									
Musculoskeletal conventional		N	N					(2)	(1)
Musculoskeletal superficial		N	N					(2)	(1)
Other									

N = new indication

Additional comments:
(1) Small organs include Thyroid, Breast and Testicles; Included within this 510(k) is imaging to assist in the placement of needles and catheters in vascular or other anatomical structures
(2) Combined is: B+B mode and B+M mode

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033604

Prescription Use ✓

Diagnostic Ultrasound Indications for Use Form

LA / 7.5MHz / L20 / 64el

Clinical application	Mode of Operation								
	A	B	M	PWD	Color Doppler	Ampl. Doppler	Color Velocity Imaging	Combined	Other
Ophthalmic									
Fetal									
Abdominal		N	N					(2)	(1)
Pediatric		N	N					(2)	(1)
Small organs		N	N					(2)	(1)
Neonatal cephalic		N	N					(2)	(1)
Cardiac									
Cardiac Pediatric									
Transesophageal									
Transrectal									
Transvaginal									
Transurethral									
Intra-operative (abdominal)		N	N					(2)	(1)
Intra-operative (vascular)		N	N					(2)	(1)
Peripheral vascular		N	N					(2)	(1)
Laparoscopic									
Musculoskeletal conventional		N	N					(2)	(1)
Musculoskeletal superficial		N	N					(2)	(1)
Other									

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

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

510(k) Number K033604