K023512

JAN 2 4 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 Hittle, Official Correspondent
8000 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
Facsimile: (317) 5779070

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FDA/CDRH/ODE/PMO

Contact Person: Colleen Densmore

Date: October 17, 2002

807.92(a)(2)

Trade Name:	Picus Ultrasound Imaging Systems	
Common Name:	Ultrasound Imaging System	
Classification Name(s):	Ultrasonic pulsed doppler imaging system Ultrasonic pulsed echo imaging system	892.1550 892.1560
Classification Number:	90IYN 90IYO	

807.92(a)(3)

Predicate Device(s)

Pie	300LC (Picus)	K002880
Esaote	AU5 3D	K000931

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

5K-3
RA

510(k) Summary
Picus 3D
Pie Medical

807.92(a)(5)

Device Description

Intended Use(s)

Pie Medical's Picus 3D ultrasound system is intended to be used by a physician to perform general diagnostic ultrasound studies including cardiac, peripheral vascular, fetal, abdominal, small organ, neonatal cephalic, transrectal and transvaginal.

510(k) Summary
Picus 3D
Pie Medical

Comparison Chart for Substantial Equivalence

General characteristics	Picus K002880	Esaote AU5 3D K000931	Pie Medical Picus 3D This submission
Transducer type			
Annular Array	No	Yes	No
Mechanical Sector	No	Yes	No
Linear	Yes	Yes	Yes
Convex	Yes	Yes	Yes
Phased array	No	Yes	No
2D Freq MHz	2.5-10	2.5 - 15	2.5 - 10
PW Freq MHz	2.5-8	2.25 - 10	2.5 - 8
CW Freq MHz	No	2.25 - 5.0	No
Probes MHz			
Annular Array	-	10 - 20	-
Linear	5.0-10	5.0 - 13	5.0 - 10
Convex	2.5-10	3.5 - 7.5	2.5 - 10
Phased array	-	2.5 - 3.5	-
Multifrequency probes	Yes	Yes	Yes
Special probes	Transvaginal	Transvaginal	Transvaginal
	Transrectal	Transrectal	Transrectal
	-	Laparoscopic	-
	-	Intraoperative	-
Biopsy attachments			
Convex	Yes	Yes	Yes
Linear	Yes	Yes	Yes
Imaging modes			
3D	No	Yes	Yes
Real time 2D	Yes	Yes	Yes
M-mode	Yes	Yes	Yes
PW Doppler	Yes	Yes	Yes
CW Doppler	No	Yes	No
CFM Doppler	Yes	Yes	Yes
Power Doppler	Yes	Yes	Yes
Triplex	Yes	Yes	Yes
Monitor size (inches)	SVGA 15	SVGA 15	SVGA 15
Programmability	10 presets	6 presets	10 presets
Pulsed Doppler	Yes	Yes	Yes
CW Doppler	No	Yes	No
Audio stereo	Yes	Yes	Yes
Color Doppler	Yes	Yes	Yes
ECG	Optional	Optional	Optional

510(k) Summary
Picus 3D
Pie Medical

General characteristics	Picus K002880	Esaote AU5 3D K000931	Pie Medical Picus 3D This submission
Digital archival capabilities	Yes	Yes	Yes
General characteristics	Picus K002880	Esaote AU5 3D K000931	Pie Medical Picus 3D
VCR	Yes	Yes	Yes
M&A Capabilities	Fetal, abdominal, small organ, neonatal cephalic, cardiac, transrectal, transvaginal & peripheral vascular	Fetal, abdominal, intraoperative abdominal, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, transrectal, transvaginal, peripheral vascular & laparoscopic	Fetal, abdominal, small organ, neonatal cephalic, cardiac, transrectal, transvaginal & peripheral vascular
Safety			
Electrical	IEC 60601-1	IEC 60601-1	IEC 60601-1
Ultrasound	Track 3 (AOD)	Track 3 (AOD)	Track 3 (AOD)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2003

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

Re: K023512
Trade Name: Picus Ultrasound Imaging System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler 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 IYN, IYO, and ITX
Dated: December 19, 2002
Received: December 20, 2002

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 Picus Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number
3.5 MHz R40 Convex array
3.5 MHz R60 Convex array
7.0 MHz R10 Convex array
7.5 MHz L40 Linear array

7.5 MHz L50 Linear array
9.5 MHz EC123 Convex array

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 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,

Nancy C Brogdon

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

Picus

System

Clinical application	Mode of Operation								
	A	B	M	PWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify) 3D
Ophthalmic									
Fetal		P	P	P	P	P			N
Abdominal		P	P	P	P	P			N
Intraoperative (specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (specify) *		P	P	P	P	P			N
Neonatal Cephalic		P	P	P	P	P			N
Adult Cephalic									
Cardiac		P	P	P	P	P			N
Transesophageal									
Transrectal		P	P	P	P	P			N
Transvaginal		P	P	P	P	P			N
Transurethral									
Intravascular									
Peripheral Vascular		P	P	P	P	P			N
Laparoscopic									
Musculo-skeletal									
Conventional									
Musculoskeletal Superficial									
Other (specify)									

N=new indication
P=previously cleared by FDA
E=added under Appendix E

Additional comments:
* Small organs include Thyroid, Breast and Testicles

Prescription Use √

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K023512

Diagnostic Ultrasound Indications for Use Form

Picus

#410501

3.5Mhz R40 Convex array

	Mode of Operation								
Clinical application	A	B	M	PWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify) 3D
Ophthalmic									
Fetal		P	P	P	P	P			N
Abdominal		P	P	P	P	P			N
Intraoperative (specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (specify) *									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal									
Transrectal									
Transvaginal									
Transurethral									
Intravascular									
Peripheral Vascular		P	P	P	P	P			N
Laparoscopic									
Musculo-skeletal									
Conventional									
Musculoskeletal Superficial									
Other (specify)									

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Prescription Use ✓

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Diagnostic Ultrasound Indications for Use Form

Picus

#410502

3.5Mhz R60 Convex array

Clinical application	Mode of Operation								
	A	B	M	PWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify) 3D
Ophthalmic									
Fetal		P	P	P	P	P			N
Abdominal		P	P	P	P	P			N
Intraoperative (specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (specify) *									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal									
Transrectal									
Transvaginal									
Transurethral									
Intravascular									
Peripheral Vascular		P	P	P	P	P			N
Laparoscopic									
Musculo-skeletal									
Conventional									
Musculoskeletal Superficial									
Other (specify)									

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Additional comments:
* Small organs include Thyroid, Breast and Testicles

Prescription Use ✓

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Diagnostic Ultrasound Indications for Use Form

Picus

#410504

7.0Mhz R10 Convex array

	Mode of Operation								
Clinical application	A	B	M	PWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify) 3D
Ophthalmic									
Fetal									
Abdominal									
Intraoperative (specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (specify) *									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal									
Transrectal		P	P	P	P	P			N
Transvaginal		P	P	P	P	P			N
Transurethral									
Intravascular									
Peripheral Vascular									
Laparoscopic									
Musculo-skeletal									
Conventional									
Musculoskeletal Superficial									
Other (specify)									

N=new indication
P=previously cleared by FDA
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Additional comments:
* Small organs include Thyroid, Breast and Testicles

Prescription Use ✓

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510(k) Number K023512

Diagnostic Ultrasound Indications for Use Form

Picus

#410503

7.5Mhz L40 Linear array

Clinical application	Mode of Operation								
	A	B	M	PWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify) 3D
Ophthalmic									
Fetal									
Abdominal									
Intraoperative (specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (specify) *		P	P	P	P	P			N
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal									
Transrectal									
Transvaginal									
Transurethral									
Intravascular									
Peripheral Vascular		P	P	P	P	P			N
Laparoscopic									
Musculo-skeletal									
Conventional									
Musculoskeletal Superficial									
Other (specify)									

N=new indication
P=previously cleared by FDA
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Additional comments:
* Small organs include Thyroid, Breast and Testicles

Prescription Use ✓

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510(k) Number K023512

Diagnostic Ultrasound Indications for Use Form

Picus

#410506

7.5Mhz L50 Linear array

	Mode of Operation								
Clinical application	A	B	M	PWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify) 3D
Ophthalmic									
Fetal									
Abdominal									
Intraoperative (specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (specify) *		P	P	P	P	P			N
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal									
Transrectal									
Transvaginal									
Transurethral									
Intravascular									
Peripheral Vascular		P	P	P	P	P			N
Laparoscopic									
Musculo-skeletal									
Conventional									
Musculoskeletal Superficial									
Other (specify)									

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Additional comments:
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Prescription Use ✓

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510(k) Number K023512

Diagnostic Ultrasound Indications for Use Form

Picus

#410729

9.5Mhz EC123 Convex array

Clinical application	Mode of Operation								
	A	B	M	PWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify) 3D
Ophthalmic									
Fetal									
Abdominal									
Intraoperative (specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (specify) *									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal									
Transrectal		E	E	E	E	E			N
Transvaginal		E	E	E	E	E			N
Transurethral									
Intravascular									
Peripheral Vascular									
Laparoscopic									
Musculo-skeletal									
Conventional									
Musculoskeletal Superficial									
Other (specify)									

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P=previously cleared by FDA
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Additional comments:
* Small organs include Thyroid, Breast and Testicles

✓

Prescription Use _____

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and Radiological Devices
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