K041675

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

Carri Graham, Official Correspondent
7992 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916, extension 103
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Contact Person: Carri Graham

Date: June 18, 2004

807.92(a)(2)

Trade Name:	Ultrasound Imaging Systems	
Common Name:	Ultrasound Imaging System	
Classification Name(s):	Ultrasonic pulsed echo imaging system Diagnostic Ultrasonic Transducer	892.1560 892.1570
Classification Number:	90IYO/90ITX	

807.92(a)(3)

Predicate Device(s)

Pie Medical	Picus	K023512 / K002880
Pie Medical	Parus	K003725
Pie Medical	100LC/100S/485	K002357
Hudson Diagnostic Imaging	Hudson 2020/2040/2060 Ultrasound Scanners	K022928

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

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

Wound imaging is a method for evaluating the extent of wounds, using high resolution ultrasound for image acquisition and applying the online measurement package of the ultrasound system to measure either the wounds' linear parameters, or the circumference and depth for volume determination. This information is used for the medical specialist to evaluate the efficacy of a particular treatment in the reduction of the wound area.

The proposed wound imaging method uses a commercially available ultrasound couplant sheet, such as the Civco's HydroScan Couplant Sheet (Class 1), to cover a wound filled with a sterile coupling gel, such as Curasol (K953450). A linear or convex array ultrasound transducer is scanned over the covered wound to image the extent of the wound. Note that it is important that the cover not be sealed with adhesive edges area, as there is a potential to cause damage to the sensitive skin area adjacent to the wound. We believe that this is a significant advantage over previously described methods which use an adhesive material on the edge of the couplant sheet, and risk damaging the sensitive skin area proximal to the wound. To prevent contamination of the wound during the scan the ultrasound probe is covered with a commercially available sterile sheath, such as those available from Civco (K970515).

The clinician can choose to perform area length or circumference measurements to evaluate the dimensions of the wound, the circumference yielding a better determination of the wounds extent in situations where the wound has an irregular geometry.

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

Pie Medical's Picus, Parus, Falco & Aquila Ultrasound Imaging Systems are to be used by or under the direction of a physician to perform general non-invasive and invasive diagnostic high resolution ultrasound imaging studies, to include: fetal, cardiac, transrectal, transvaginal, abdominal, neonatal cephalic, pediatric, peripheral vascular, small organs, intraoperative abdominal, intraoperative vascular, musculoskeletal (conventional and superficial) and wounds.

8007.92(a)(6) Technological Characteristics

General characteristics	[1] Pie Medical Picus, Parus, Falco & Aquila Systems This Submission	Pie Medical Picus, Parus, Falco & Aquila Systems K002880/023513/ 003725	Hudson Diagnostic Imaging Hudson 2020/2040/2060 Systems K022928
Intended Use			
Fetal, Abdominal, Pediatric, Small Organ, Intraoperative abdominal, Peripheral vascular, Cardiac, Transrectal, Transvaginal, Musculoskeletal-conventional & superficial, Abdominal, Neonatal Cephalic & Wounds	Fetal, Abdominal, Pediatric, Small Organ, Intraoperative abdominal, Peripheral vascular, Cardiac, Transrectal, Transvaginal, Musculoskeletal-conventional & superficial, Abdominal, Neonatal Cephalic & Wounds	Fetal, Abdominal, Pediatric, Small Organ, Intraoperative abdominal, Peripheral vascular, Cardiac, Transrectal, Transvaginal, Musculoskeletal-conventional & superficial, Abdominal, Neonatal Cephalic & Wounds	Wounds
Transducer Type			
Linear	8.0 Mhz 30C/40mm (#410647) 7.5 Mhz 40mm (#410503)	8.0 Mhz 30C/40mm (#410647) 7.5 Mhz 40mm (#410503)	8.0 Mhz 40mm (#402198) 6-8 Mhz 60mm (#410054) 5.0 Mhz 40mm (#410503)

8007.92(a)(6) **Technological Characteristics**

General characteristics	Pie Medical Picus, Parus, Falco & Aquila Systems This Submission	Pie Medical Picus, Parus, Falco & Aquila Systems K002880/023513/ 003725	Hudson Diagnostic Imaging Hudson 2020/2040/2060 Systems K022928
Imaging Modes	2D / M-mode	2D / M-mode 3D (Picus)	2D / M-mode
Safety			
Electrical Safety	EN60601-1	EN60601-1	EN60601-1
Ultrasound Safety	Track 1/3	Track 1/3	Track 1/3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2004

Pie Medical
% Ms. Carrie Graham
Consultant
The Anson Group
7992 Castleway Drive
INDIANAPOLIS IN 46250

Re: K041675
Trade Name: Picus, Parus, Falco, and Aquila Ultrasound Imaging System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Name: 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: June 18, 2004
Received: June 21, 2004

Dear Ms. Graham:

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, Parus, Falco, and Aquila Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

7.5 MHz L40, Picus
8MHz LA DF 30C/40mm, Parus, Falco, & Aquila

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,

David A. Lepore

for 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 - Appendix F

Parus System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P						P [2]	
Abdominal		P	P						P [2]	
Intraoperative (Abdominal)		P	P							
Intraoperative Neurological										
Pediatric		P	P						P [2]	
Small Organ (specify) [1]		P	P						P [2]	
Neonatal Cephalic		P	P						P [2]	
Adult Cephalic										
Cardiac		P	P						P [2]	
Transesophageal										
Transrectal		P	P						P [2]	
Transvaginal		P	P						P [2]	
Transurethral										
Intravascular										
Peripheral Vascular		P	P						P [2]	
Laparoscopic										
Musculo-skeletal Conventional		P	P						P [2]	
Musculo-skeletal Superficial		P	P						P [2]	
Other - Wounds		N								

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

Additional Comments:

[1] Small organs include Thyroid, Breast and Testicles.

[2] Applicable combined modes: B+B; B+M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041675

Diagnostic Ultrasound Indications for Use Form - Appendix F

Falco System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P						P [2]	
Abdominal		P	P							
Intraoperative (Abdominal)		P	P						P [2]	
Intraoperative Neurological										
Pediatric		P	P						P [2]	
Small Organ (specify) [1]		P	P						P [2]	
Neonatal Cephalic		P	P						P [2]	
Adult Cephalic										
Cardiac		P	P						P[2]	
Transesophageal										
Transrectal		P	P							
Transvaginal		P	P							
Transurethral										
Intravascular										
Peripheral Vascular		P	P						P [2]	
Laparoscopic										
Musculo-skeletal Conventional		P	P						P [2]	
Musculo-skeletal Superficial		P	P						P [2]	
Other - Wounds		N								

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

Additional Comments:

[1] Small organs include Thyroid, Breast and Testicles.

[2[Applicable combined modes: B+B; B+M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lazarus

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041675

Diagnostic Ultrasound Indications for Use Form - Appendix F

Aquila System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P						P [2]	
Abdominal		P	P						P [2]	
Intraoperative (Abdominal)		P	P						P [2]	
Intraoperative Neurological										
Pediatric		P	P						P [2]	
Small Organ (specify) [1]		P	P						P [2]	
Neonatal Cephalic		P	P						P [2]	
Adult Cephalic										
Cardiac		P	P						P [2]	
Transesophageal										
Transrectal		P	P						P [2]	
Transvaginal		P	P						P [2]	
Transurethral										
Intravascular										
Peripheral Vascular		P	P						P [2]	
Laparoscopic										
Musculo-skeletal Conventional		P	P						P [2]	
Musculo-skeletal Superficial		P	P						P [2]	
Other - Wounds		N								

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

Additional Comments:

[1] Small organs include Thyroid, Breast and Testicles.

[2] Applicable Combined Modes: B+B; 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,
and Radiological Devices
510(k) Number K041675

Diagnostic Ultrasound Indications for Use Form - Appendix F

Picus System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD (D)	CWD	Color Doppler (CD)	Amplitude Doppler (AD)	Color Velocity Imaging	Combined (specify)	Other (specify) 3D
Ophthalmic										
Fetal		P	P	P		P	P		P[2]	P
Abdominal		P	P	P		P	P		P[2]	P
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify) [1]		P	P	P		P	P		P[2]	P
Neonatal Cephalic		P	P	P		P	P		P[2]	P
Adult Cephalic										
Cardiac		P	P	P		P	P		P[2]	P
Transesophageal										
Transrectal		P	P	P		P	P		P[2]	P
Transvaginal		P	P	P		P	P		P[2]	P
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P		P[2]	P
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		P[2]	
Musculo-skeletal Superficial		P	P	P		P	P		P[2]	
Other - Wounds		N								

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

Additional Comments:

[1] Small organs include Thyroid, Breast and Testicles.

[2] Applicable combined modes: B+D; B+CD+D; B+AD+D

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041675

Diagnostic Ultrasound Indications for Use Form - Appendix F

Probe #410503 - Picus
7.5 MHz L40

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

	Mode of Operation									
Clinical Application	A	B	M	PWD (D)	CWD	Color Doppler (CD)	Amplitude Doppler (AD)	Color Velocity Imaging	Combined (specify)	Other (specify) 3D
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify) [1]		P	P	P		P	P		P [2]	P
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P		P [2]	P
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		P[2]	
Musculo-skeletal Superficial		P	P	P		P	P		P[2]	
Other - Wounds		N								

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

Additional Comments:

[1] Small organs include Thyroid, Breast and Testicles.

[2] Applicable combined modes: B+D; B+CD+D; B+AD+D

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Seyram

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041675

Diagnostic Ultrasound Indications for Use Form - Appendix F

Probe# 410647 – Parus, Falco & Aquila
8MHz LA DF 30C/40mm

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify) 3D
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)		P	P						P [2]	
Intraoperative Neurological										
Pediatric		P	P						P [2]	
Small Organ (specify) [1]		P	P						P [2]	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P						P [2]	
Laparoscopic										
Musculo-skeletal Conventional		P	P						P [2]	
Musculo-skeletal Superficial		P	P						P [2]	
Other - Wounds		N								

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

Additional Comments:

[1] Small organs include Thyroid, Breast and Testicles.

[2] Applicable combined modes: B+B; B+M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041675