K100598

Summary of Safety and Effectiveness

NOV 19 2010

This summary of 510(k) safety and effectiveness information is submitted as a part of this Premarket Notification in accordance with the requirements of the Safe Medical Devices Act of 1990 as implemented in 21 CFR 807.92.

1) Submitter's information:

Penrith Corporation
5170 Campus Drive Suite 2
Plymouth Meeting, PA 19462 USA

Corresponding official:	Lawrence Engle
Email:	lengle@penrithcorp.com
Telephone:	610 834 1220
Fax:	610 834 1220

Date Summary Prepared: February 10, 2010

2) Device Information

The proprietary name of the device is the Penrith Elettra Diagnostic Ultrasound System.

The Elettra is classified as follows:

90 IYN Ultrasonic Pulsed Doppler Imaging System
90 IYO Ultrasonic Pulsed Echo Imaging System
90 ITX Diagnostic Ultrasound Transducer

The Penrith Elettra is a compact diagnostic ultrasound device. It includes a system console housing electronic circuitry, a video display, power supply, and user controls. This connects to the transducers and together these generate the ultrasound image.

The Penrith Elettra is intended to be used by a qualified physician for diagnostic imaging or fluid flow analysis of the human body including: Fetal,

Abdominal, Intraoperative, Intraoperative Neurological, Pediatric, Small Organ, Neonatal Cephalic, Cardiac, Peripheral Vessel, Musculoskeletal (Conventional), and Musculoskeletal (Superficial).

The Company believes that the Penrith Elettra is substantially equivalent to the Acuson Sequoia, K022567, the Acuson Cypress K052331, and the Philips Avalon CTS, K023931.

The Penrith Elettra system and transducers function in a manner that is substantially equivalent to the previously cleared devices: Predicate device systems and the Elettra transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. The Elettra and the predicate devices share basic scanning modalities. Some or all predicate device systems allow for measurements of structures and flow, and calculations. Some or all predicate devices and the Elettra follow the Track 3 method for acoustic output. Patient contact materials used in the Elettra are used in equivalent formulations in the predicate devices. All indications for use claimed for the Elettra are cleared indications found on some or all of the predicate devices. The Elettra ultrasound transducer may be used in a wireless configuration or in a cabled configuration. The Elettra and the predicate devices have been designed and manufactured under comparable electrical and physical safety standards.

The Penrith Elettra has been evaluated for acoustic output, biocompatibility, cleaning, disinfection, and sterilization effectiveness, as well as thermal, electrical and mechanical safety, and electromagnetic compatibility. It has been found to conform with applicable medical device safety standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Penrith Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Servies, LLC
1394 25th Street NW
BUFFALO MN 55313

NOV 19 2010

Re: K100598
Trade/Device Name: Penrith Elettra Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: October 18, 2010
Received: October 19, 2010

Dear Mr. Job:

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 Penrith Elettra Ultrasound System, as described in your premarket notification:

Transducer Model Number

L8-3 Linear
L12-5 Linear
C5-2 Curvilinear

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 895. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Section 1.3 Indications for Use

K100598

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The Elettra Ultrasound System is intended for diagnostic imaging or fluid flow analysis of the human body including: Fetal, Abdominal, Intraoperative, Intraoperative Neurological, Pediatric, Small Organ, Neonatal Cephalic, Cardiac, Peripheral Vessel, Musculoskeletal (Conventional), Musculoskeletal (Superficial). See Indications for Use Forms below. The following tables provide details regarding clinical applications and modes of operation for the system and individual transducers.

Prescription Use **X** (Part 21 CFR 801 Subpart D)	AND/OR	Over-the-Counter Use ____ (21 CFR Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Devices
Evaluation and Safety

510(k) K100598

Indications for Use Form

510(k) Number (if known): K100598

Device Name: Penrith Elettra Ultrasound System

Indications for Use: Diagnostic Imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify) Note 2	Other: Harmonic Imaging
Opthalmic										
Fetal		N				N	N			
Abdominal		N				N	N			
Intraoperative Note 1		N				N	N			
Intraoperative Neurological		N				N	N			
Pediatric		N				N	N			
Small Organ Note 3		N				N	N			
Neonatal Cephalic		N				N	N			
Adult Cephalic										
Cardiac		N				N	N			
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		N				N	N			
Laparoscopic										
Musculo-skeletal Conventional		N				N	N			
Musculo-skeletal Superficial		N				N	N			
Other										

N: New P: Previously Cleared Blank: Not Claimed

Note 1: for example: cardiac

Note 2: B mode and PWD mode or Color Doppler and PW mode

Note 3: for example: breast, testes, thyroid, penis

Prescription Use **X** (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use ____ (21 CFR Subpart C)

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510(k) K100598

Indications for Use Form

510(k) Number (if known): K100598

Device Name: L8-3 Linear Transducer for use with Penrith Elettra Ultrasound System

Indications for Use: Diagnostic Imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify) Note 2	Other: Harmonic Imaging
Opthalmic										
Fetal		N				N	N			
Abdominal		N				N	N			
Intraoperative Note 1		N				N	N			
Intraoperative Neurological		N				N	N			
Pediatric		N				N	N			
Small Organ Note 3		N				N	N			
Neonatal Cephalic		N				N	N			
Adult Cephalic										
Cardiac		N				N	N			
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		N				N	N			
Laparoscopic										
Musculo-skeletal Conventional		N				N	N			
Musculo-skeletal Superficial		N				N	N			
Other										

N: New P: Previously Cleared Blank: Not Claimed

Note 1: for example: cardiac

Note 2: B mode and PWD mode or Color Doppler and PW mode

Note 3: for example: breast, testes, thyroid, penis

Prescription Use **X** (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use ____ (21 CFR Subpart C)

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510(k) K100598

Indications for Use Form

510(k) Number (if known): K100598

Device Name: L12-5 Linear Transducer for use with Penrith Elettra Ultrasound System

Indications for Use: Diagnostic Imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify) Note 2	Other: Harmonic Imaging
Opthalmic										
Fetal		N				N	N			
Abdominal		N				N	N			
Intraoperative Note 1		N				N	N			
Intraoperative Neurological		N				N	N			
Pediatric		N				N	N			
Small Organ Note 3		N				N	N			
Neonatal Cephalic		N				N	N			
Adult Cephalic										
Cardiac		N				N	N			
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		N				N	N			
Laparoscopic										
Musculo-skeletal Conventional		N				N	N			
Musculo-skeletal Superficial		N				N	N			
Other										

N: New P: Previously Cleared Blank: Not Claimed

Note 1: for example: cardiac

Note 2: B mode and PWD mode or Color Doppler and PW mode

Note 3: for example: breast, testes, thyroid, penis

Prescription Use **X** (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use ____ (21 CFR Subpart C)

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510(k) K100598

Indications for Use Form

510(k) Number (if known): K100598

Device Name: C5-2 Curvilinear Transducer for use with Penrith Elettra Ultrasound System

Indications for Use: Diagnostic Imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify) Note 2	Other: Harmonic Imaging
Opthalmic										
Fetal		N				N	N			
Abdominal		N				N	N			
Intraoperative Note 1		N				N	N			
Intraoperative Neurological		N				N	N			
Pediatric		N				N	N			
Small Organ Note 3		N				N	N			
Neonatal Cephalic		N				N	N			
Adult Cephalic										
Cardiac		N				N	N			
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vessel		N				N	N			
Laparoscopic										
Musculo-skeletal Conventional		N				N	N			
Musculo-skeletal Superficial		N				N	N			
Other										

N: New P: Previously Cleared Blank: Not Claimed

Note 1: for example: cardiac

Note 2: B mode and PWD mode or Color Doppler and PW mode

Note 3: for example: breast, testes, thyroid, penis

Prescription Use **X** (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use ____ (21 CFR Subpart C)

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