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VIASYS™
HEALTHCARE
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NEUROCARE GROUP

Nicolet Biomedical • GSI • Nicolet Vascular

510(k) Summary

JAN 2 4 2006

Company Name: VIASYS NEUROCARE
5225 Verona Road
Madison, WI 53711

Contact: Glen Hermanson, Global Manager, Quality Engineering
Phone: 608 441-2065
Fax: 608 441-2007

Summary Date: December 27, 2005

Trade Name: Pioneer TC8080, Companion III

Common Name: Ultrasonic Pulsed Doppler Imaging System

Classification Name: 21 CFR 882.1550; Product Code: IYN
21 CFR 892.1579; Product Code: ITX

Predicate Device(s):

510(k) Number: K864695
Manufacture: EME
Trade Name: EME TC2-64B

510(k) Number: K020754
Manufacture: Nicolet Biomedical
Trade Name: Pioneer TC8080

510(k) Number: K011224
Manufacture: Advanced Technology Laboratories, Inc.
Trade Name: HDI® 5000 Ultrasound System

1.0 Description of Device

The modified Pioneer TC8080 and Companion III are Doppler ultrasound systems. Both systems utilize the well-understood principle of Doppler shift to detect the flow of blood within the body. The ultrasound probe generates ultrasonic energy, which is coupled to the body. The ultrasonic energy, which is reflected from the moving blood in blood vessels and

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the returning signal, is detected as a frequency shifted signal. The amount of frequency shift is a function of the velocity of the flowing blood. These systems generate, transmit and receive an ultrasonic signal, then process and display the Doppler signal returning from the anatomy.

The Pioneer TC8080 can be used with up to four Doppler ultrasound probes simultaneously. The Companion III, applying the same software and hardware as the Pioneer TC8080, can be used with up to two Doppler ultrasound probes simultaneously.

2.0 Intended Use

The modified Pioneer TC8080 and Companion III are applied to indicate blood flow by application of Doppler ultrasound technology. Reference the accompanying Indication for Use Forms.

3.0 Technological

Doppler ultrasound probes with a variety of modes of operation are available for use with the systems. The 1.6 MHz probe is an unfocussed pulsed wave Doppler probe (PW). The 2 MHz probes (15-mm diameter and 10 mm diameter) are unfocussed PW Doppler probes. The 4 MHz and 8 MHz probes are unfocussed probes that operate in continuous wave (CW) or PW Doppler mode. The 16 MHz and 20 MHz Microvascular probes (1.5 mm and 2.0 mm diameter) are unfocussed PW Doppler probes. The ultrasound probes do not directly contact the blood and are not implantable.

4.0 Conclusions

The indications, intended use and technology of the modified Pioneer TC8080 and Companion III devices are substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2006

Viasys Neurocare
% Mr. Gary Syring
Principle Consultant
Quality & Regulatory Associates, LLC
800 Levanger Lane
STOUGHTON WI 53589

Re: K053648
Trade Name: Pioneer TC8080 / Companion III Doppler Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYN and ITX
Dated: December 27, 2005
Received: December 30, 2005

Dear Mr. Syring:

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 Pioneer TC8080 / Companion III Doppler Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

1.6 MHz Probe
2 MHz Probe
4 MHz Probe
8 MHz Probe
16 MHz Probe
20 MHz Probe

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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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)

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound 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)	Other (specify)
Ophthalmic				N						
Fetal										
Abdominal										
Intraoperative (specify)				N						
Intraoperative Neurological				N						
Pediatric				N						
Small Organ (specify)										
Neonatal Cephalic				N						
Adult Cephalic				P						
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P	P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: P – Cleared to market by 510(k) K020754

The Pioneer TC8080 applies ultrasound probes of 1.6 MHz Pulsed Wave (PW), 2 MHz PW, 4 MHz PW and Continuous Wave (CW), 8 MHz PW/CW, 16 MHz PW and 20 MHz PW. Intraoperative: Transcranial and Intracranial Doppler Monitoring, Carotid Monitoring, Microvascular Blood Flow, Emboli Detection.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053648

Companion III

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound 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)	Other (specify)
Ophthalmic				N						
Fetal										
Abdominal										
Intraoperative (specify)				N						
Intraoperative Neurological				N						
Pediatric				N						
Small Organ (specify)										
Neonatal Cephalic				N						
Adult Cephalic				E						
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				E	E					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: E – Cleared to market by 510(k) K020754 as a non-significant change to The Pioneer TC8080. The Companion III applies ultrasound probes of 1.6 MHz Pulsed Wave 2 MHz PW, 4 MHz PW and Continuous Wave (CW), 8 MHz PW/CW, 16 MHz PW and 20 MHz PW. Intraoperative: Transcranial and Intracranial Doppler Monitoring, Carotid Monitoring, Microvascular Blood Flow, Emboli Detection.

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510(k) Number K053648

1.6 MHz Probe for Pioneer TC8080 and Companion III

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Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound 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)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)				N						
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic				P						
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: P Cleared to market by 510(k) K020754

Intraoperative: Transcranial Doppler Monitoring, Emboli Detection.

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510(k) Number K053648

2 MHz Probe for Pioneer TC8080 and Companion III

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound 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)	Other (specify)
Ophthalmic				N						
Fetal										
Abdominal										
Intraoperative (specify)				N						
Intraoperative Neurological										
Pediatric				N						
Small Organ (specify)										
Neonatal Cephalic				N						
Adult Cephalic				P						
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				N						
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: P – Cleared to market by 510(k) K020754

Two crystal diameters are indicated: 10 mm diameter and 15 mm diameter

Intraoperative: Transcranial Doppler Monitoring, Carotid Monitoring, Emboli Detection.

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Prescription Use (Per 21 CFR 801.109)

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510(k) Number K053648

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound 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)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)				N						
Intraoperative Neurological										
Pediatric				N						
Small Organ (specify)										
Neonatal Cephalic				N						
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P	P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: P – Cleared to market by 510(k) K020754

Intraoperative: Extracranial carotid monitoring.

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Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound 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)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)				N						
Intraoperative Neurological										
Pediatric				N						
Small Organ (specify)										
Neonatal Cephalic				N						
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P	P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: P Cleared to market by 510(k) K020754

Intraoperative: Extracranial carotid monitoring.

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510(k) Number K053648

16 MHz Probe for Pioneer TC8080 and Companion III

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound 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)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)				N						
Intraoperative Neurological				N						
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: P - Cleared to market by 510(k) K020754

Two crystal diameters are indicated: 1.5 mm diameter and 2.0 mm diameter

Intraoperative: Microvascular Blood Flow.

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053648

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound 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)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)				N						
Intraoperative Neurological				N						
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: P - Cleared to market by 510(k) K020754

Two crystal diameters are indicated: 1.5 mm diameter and 2.0 mm diameter

Intraoperative: Microvascular Blood Flow.

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