K060112

Nodecrest LLC

MAY - 5 2006

SUMMARY STATEMENT

Contact Person:	David G. Pegler
Address:	Nodecrest LLC 1478 Powells Tavern Place Herndon, Virginia 20170
Phone:	703-627-6636

Classification Name:	System, Imaging, Pulsed Doppler, Ultrasonic
Common Usual Name:	Transcranial Doppler Ultrasound System
Classification:	Class II
Product Code:	90 IYN
Classification Panel:	Radiology

Device Description

The EMS9U range is a Transcranial Doppler (TCD) diagnostic ultrasound system, with a pulse wave and / or continuous wave Doppler transducer that can be used free hand (or head frame mounted for longer term monitoring). A supplementary M-mode display may be used to help locate blood flow signals to position the sample gate for Doppler signal, and for detection of emboli signals. Each of the three models in the range is identical in terms of hardware the difference being features that the end user does not request are turned off in the software.

Intended Use

The range of Nodecrest Transcranial Doppler Ultrasound System is intended for use as a diagnostic ultrasound fluid flow analysis system:

1) For the measurement of cerebral artery blood velocities to determine the presence of hemodynamically significant deviations from normal values

2) To assess arterial cerebral blood flow for the occurrence of micro embolic signals. Vessels intended for observation include, but are not limited to the middle, anterior and posterior cerebral arteries, via the temporal windows, the

vertebral mid basilar arteries via the foramen magnum and the ophthalmic artery and intracranial internal carotid artery via the eye.

The Nodecrest Transcranial Doppler is intended for use during:

a) Diagnostic exams
b) Surgical interventions

The device is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.

12.1 Product Comparison Chart

Parameters	Nodecrest	Rimed Ltd.
510(k) Number		K974588
Transducer Frequency	2MHz, 4MHz, 8MHz	2MHz, 4MHz, 8MHz
Frequency Spectrum	FFT 256/512 dots	64/512 dots
Frequency Ranges	1 to 16 MHz	2 to 32 MHz
Depth Measurement	5 to 136 mm	15-150 mm
Gain	0 ~ 40db	Manually control 20 steps
Clinical Application for: 2MHz		
PWD	Ophthalmic, Adult Cephalic & Peripheral Vascular	Ophthalmic, Adult Cephalic
CWD	Ophthalmic & Peripheral Vascular	Ophthalmic & Peripheral Vascular
Clinical Application for: 4MHz		
PWD	Peripheral Vascular	
CWD	Peripheral Vascular	Peripheral Vascular
Clinical Application for: 8MHz		
PWD	Peripheral Vascular	
CWD	Peripheral Vascular	Ophthalmic & Peripheral Vascular
General Electrical Testing	IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, UL 2601-1	EN 60601-1-1 & EN 60601-1-2
Biocompatibility Tests		
ISO 10993	Cytotoxicity, Sensitization,	Unknown

	skin irritation	
USP	Acute Toxicity, Intracutaneous Reactivity, Implantation & Cytotoxicity	Unknown

12.2 Summary of Safety and Effectiveness:

The Nodecrest Transcranial Doppler Ultrasound System and the Rimed Smart-Lite™ Transcranial Doppler have similar intended use: both offer similar transducer frequency, frequency spectrum, frequency ranges, depth measurement, gain, and offer similar clinical applications. Both systems meet IEC 60601-1 & IEC 60601-1-2 Standards for general electrical safety of medical devices and electrical emissions.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nodecrest, LLC
% Mr. E. J. Smith
President
Smith Associates
1676 Village Green, Suite A
CROFTON MD 21114

MAY - 5 2006

Re: K060112
Trade Name: Nodecrest Transcranial Doppler Ultrasound System
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: March 1, 2006
Received: March 2, 2006

Dear Mr. Smith:

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 Nodecrest Transcranial Doppler Ultrasound System, as described in your premarket notification:

Transducer Model Number

2 MHz
4 MHz
8 MHz

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 Andrew Kang, M.D. at (301) 594-1212.

Sincerely yours,

David A. Gross

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (If known): K060112

Device Name: Nodecrest Transcranial Doppler Ultrasound System

Indications for Use:

The range of Nodecrest Transcranial Doppler Ultrasound System is intended for use as a diagnostic ultrasound fluid flow analysis system:

1) For the measurement of cerebral artery blood velocities to determine the presence of hemodynamically significant deviations from normal values

2) To assess arterial cerebral blood flow for the occurrence of micro embolic signals. Vessels intended for observation include, but are not limited to the middle, anterior and posterior cerebral arteries, via the temporal windows, the vertebral mid basilar arteries via the foramen magnum and the ophthalmic artery and intracranial internal carotid artery via the eye.

The Nodecrest Transcranial Doppler is intended for use during:

a) Diagnostic exams
b) Surgical interventions

The device is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lagerlund

(Division Sign-Off)
Division of Reproductive, Abdominal,
ar[illegible]vices
510(k) Number K060112

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				X						
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic				X						
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				X						
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: EMS 9U TRANSCRANIAL Doppler System 2 MHz Probe

(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)

David A. Lagomarsino

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K960112

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)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				X	X					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: EMS 90 TRANSCRANIAL DOPPLER SYSTEM 4 MHz PROBE

(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)

David A. Lyerly

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K060112

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)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				X	X					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: EMSDU TRANSCRANIAL DOPPLER SYSTEM 8MHz PROBE

(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)

F-3

Daniel A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060112