SEP 6 2002

K021858

Attachment E:
Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92(c).

510(k) Summary of Safety and effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMD 1990 and 21 CFR 807.92.

The assigned 510(k) number is:_____

Applicant Information:

Date Prepared: March 18, 2002

Name: Novasonics, Inc.
1061 Terra Bella Ave.
Mountain View, CA 94043

Contact Persons: Cheryl A. Blake
Director, Quality Assurance
Regulatory Affairs

Telephone Numbers: 650-230-2715

Fax Number: 650-230-2818

Device Information:

Classification: Class II

Trade Name: Novasonics SuperNova Ultrasound System

Common Name: Diagnostic Ultrasound System

Device Name: Nova Plus Diagnostic Ultrasound System

	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

Marketed Device(s): The HDI 5000: K002003 and the GE LOGIC 9: K011188

Device Description: The SuperNova is a general purpose diagnostic ultrasound system. It consists of a Personal Display Unit approximately 4 inches wide and 3 inches high that can be held by the user in one hand and includes buttons for controlling the system and a screen that display ultrasound mages and user interface . The Imaging Unit can be held by the user in one hand and accommodates a removable transducer module. Signals received from the transducer module are digitized and preprocessed. The transducer module comes into contact with the patient and both transmits and receives ultrasound energy

The docking station provides holders for the Personal Display Unit, the Imaging Unit, and transducer modules, as well as battery chargers.

Indications For Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Intra-operative (abdominal, thoracic, and vascular); Intra-operative Neuro; Pediatric; Small Organ (Thyroid, Breast, Testes, etc.); Neonatal Cephalic; Adult Cephalic; Trans-rectal; Trans-

vaginal; Trans-esoph. (non-cardiac); Cardiac Adult; Cardiac Pediatric; Trans-esoph (Cardiac), Peripheral Vessel.

Comparison with Predicate Device: The SuperNova ultrasound system equipped with Doppler and Harmonic imaging modes is substantially equivalent from both a transducer and user point of view to the Phillips ATL HDI® 5000 or the GE Logiq 9™ systems, that are currently in commercial distribution in the United States. Since the SuperNova unit has intended uses and functional modes that are a subset of these approved devices it is felt that the SuperNova unit meets the criteria for substantial equivalence as required for 510(k) filling.

The technological characteristics utilized in design, construction, and materials are similar, and have the same intended uses and basic operating modes as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 6 2002

Novasonics, Inc.
% Mr. Mark Job
Program Manager
TÜV Product Service, Inc.
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K022858
Trade Name: SuperNova Diagnostic Ultrasound Scanning 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: August 23, 2002
Received: August 28, 2002

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 SuperNova Diagnostic Ultrasound Scanning System, as described in your premarket notification:

Transducer Model Number

C^4_2
S^4_2

$$\frac{EV^8_4}{L^{10}_5}$$

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 (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,

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

Enclosure(s)

K022858

Draft

SuperNova System with Doppler and Harmonic Imaging Modes

Transducer: SuperNova System (Union of all Transducer Types)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N	N	N	N	N
	Abdominal	N	N	N	N	N	N	N
	Intra-operative (Specify)[6]	N	N	N		N	N	N
	Intra-operative (Neuro)	N		N		N	N	N
	Laparoscopic							
	Pediatric	N	N	N	N	N	N	N
	Small Organ (Thyroid, Breast, Testes, etc.)	N	N	N		N	N	N
	Neonatal Cephalic	N	N	N	N	N	N	N
	Adult Cephalic	N	N	N	N	N	N	N
	Trans-rectal	N	N	N		N	N	N
	Trans-vaginal	N	N	N		N	N	N
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N	N	N	N	N
	Cardiac Pediatric	N	N	N	N	N	N	N
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel	N	N	N		N	N	N
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under Appendix E
[1] Includes B-Mode and Harmonic imaging (HI)
[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)
[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)
[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)
[5] Color M-Mode (CM)
[6] Intraoperative includes abdominal, thoracic (cardiac) and vascular (PV)

David C. Hagen
(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K022858

Prescription Use ✓

SuperNova System with Curvilinear Transducer PN 84001

System: SuperNova System with Doppler and Harmonic Imaging modes

Transducer: C_2^4

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	N
	Abdominal[6]	N	N	N		N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel	N	N	N		N	N	N
	Other (Specify)							

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

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

Prescription Use ✓

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022858

SuperNova System with Phased (Sector) Array Transducer PN 84004

System: SuperNova System with Doppler and Harmonic Imaging modes

Transducer: S_2^4

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N	N	N	N	N
	Abdominal[6]	N	N	N	N	N	N	N
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N	N	N	N	N
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	N	N	N	N	N	N	N
	Adult Cephalic	N	N	N	N	N	N	N
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N	N	N	N	N
	Cardiac Pediatric	N	N	N	N	N	N	N
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Specify)							

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

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022858

SuperNova System with Endo-Vaginal Transducer PN 84002

System: SuperNova System with Doppler and Harmonic Imaging modes

Transducer: EV_4^8

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	N
	Abdominal							
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	N	N
	Trans-vaginal	N	N	N		N	N	N
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Specify)							

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

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

Prescription Use ✓

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022858

SuperNova System with Linear Transducer PN 84003

System: SuperNova System with Doppler and Harmonic Imaging modes

Transducer: L_5^{10}

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	N
	Abdominal[6]	N	N	N		N	N	N
	Intra-operative (Specify)[7]	N	N	N		N	N	N
	Intra-operative (Neuro)	N		N		N	N	N
	Laparoscopic							
	Pediatric	N	N	N		N	N	N
	Small Organ (Thyroid, Breast, Testes, etc.)	N	N	N		N	N	N
	Neonatal Cephalic	N	N	N		N	N	N
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)[8]							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel	N	N	N		N	N	N
	Other (Specify)							

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

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative includes abdominal, thoracic (cardiac) and vascular (PV)

Prescription Use ✓

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022858