

### SECTION 3

#### 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR 807, Subpart E, Section 807.7.

1. Classification Name

Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560  
Product Code: 90-IYO

Diagnostic Ultrasonic Transducer, 21 CFR 892.1570  
Product Code: 90-ITX

Common/ Usual Name

Diagnostic Ultrasound System with Accessories

Proprietary Name

Sonopsy LA System

2. Establishment Information

The Sonopsy LA System was designed and developed by NeoVision, a Division of United States Surgical Corporation, of 1700 Westlake Avenue North, Seattle, WA 98109. The FDA has assigned NeoVision an establishment registration number of 3029061.

3. Class

Class II, Tier 2.

NeoVision believes that the Sonopsy LA System is substantially equivalent to the following products FDA has classified as Class II devices:

- Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560
- Diagnostic Ultrasonic Transducer, 21 CFR 892.1570

4. Performance Standards

None established under Section 514. However, the Sonopsy LA System has been designed to comply with the following voluntary performance standards:

- UL-2601 Medical Electrical Equipment, Part 1: General Requirement for Safety
- CSA C22.2 Electromedical Devices, National Deviations No. 125-601.1
- IEC 601-1-1 Safety of Medical Equipment, Type B, Class 1

5. Special Controls

The Sonopsy LA System is subject to the 510(k) Special Report requirement that applies to all diagnostic ultrasound systems.

6. Device Description

The Sonopsy LA System provides a means for performing a volumetric scan of the breast to image and determine the position of a suspect target. For biopsy procedures, the Sonopsy LA System allows the alignment of an integral needle guidance device that insures that the needle will sample along a line that includes the determined target. The real-time ultrasound image is aligned such that the scan plane corresponds to the plane that the needle will penetrate, which enables the user to make a determination that the needle penetrated to the target area (by virtue of the real-time image).

The system operates in B-mode with an automatic scanning annular array transducer for breast applications and a hand-held linear array scanhead for small organ and abdominal imaging.

7. General Safety and Effectiveness

The device labeling contains instructions for use to assure the safe and effective use of the device. The device is a prescription device and the labeling indicates the device must be used by or on the order of a physician. Testing of patient contact materials in accordance with the FDA memorandum Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" indicates that none of the patient or user contact materials pose a biocompatibility risk.

8. Acoustic Output

The Sonopsy LA System is a Track 1 device with application specific maximum limits as follows:

	$I_{SPTA.3}$	94 mW/cm <sup>2</sup>
and	$I_{SPPA.3}$	190 W/cm <sup>2</sup>
or	Mechanical Index (MI)	1.9

The acoustic output will be measured and calculated per the December, 1985, 510(k) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices, except that the hydrophone will meet the requirements of the Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment (NEMA, UD 2, revision 2). Measurement results will be maintained in the Device Master Record for this device and maximum output values will also be reported in the Operator's Manual.

Substantial equivalence for output reporting will follow the TRACK 1 path per FDA's Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, dated September 30, 1997.

9. Predicate Device

NeoVision believes that the Sonopsy LA System, with the features described in this notification and when used in combination with the transducers included in this notification, is substantially equivalent to the NeoVision Sonopsy System and the Siemens SONOLINE Prima Digital Ultrasound System.

10. Software

Software development for the Sonopsy LA System follows NeoVision's documented process for software design, verification and validation testing. A hazards analysis has been conducted to identify potential equipment design hazards that could cause a diagnostic error or injury to the patient, user, or service personnel and appropriate steps have been taken to control all identified risks for this type of ultrasound equipment.

11. Conclusions

NeoVision's Sonopsy LA System diagnostic ultrasound device and transducers are designed and manufactured to meet United States and international diagnostic ultrasound and electromedical equipment safety standards. The system and its transducers have essentially the same intended uses and technological characteristics and are substantially equivalent to previously 510(k)-cleared diagnostic ultrasound systems.

12. Submitted by

Jamie Yieh  
Regulatory Affairs, Associate

Contact Person

Victor M. Clavelli  
Manager, Regulatory Affairs

United States Surgical Corporation  
150 Glover Avenue  
Norwalk, Connecticut 06856

(203) 845-4543 - Phone

(203) 845-4503 - Fax



AUG -7 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Victor M. Clavelli  
Program Manager, Regulatory Affairs  
United States Surgical Corporation  
150 Glover Avenue  
Norwalk, Connecticut 06856

Re: K980423  
Sonopsy™ LA System  
Regulatory Class: II/21 CFR 892.1560  
Product Code: 90 IYO  
Dated: July 1, 1998  
Received: July 2, 1998

Dear Mr. Clavelli:

We have reviewed your Section 510(k) 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 Sonopsy LA System, as described in your premarket notification:

Transducer Model Number

7.5 MHz Annular Array  
7.5/5.0 MHz Linear Array

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosures

### 4.3 INDICATIONS FOR USE

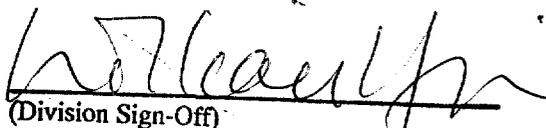
The intended use of the Sonopsy LA System is as a diagnostic ultrasound imaging system of the human body as follows:

Mode of Operation:	B-Mode
Clinical Application:	Small Organ (breast, thyroid, testes) Abdominal

The Sonopsy LA System is indicated for use as an adjunct to mammography for B-mode ultrasonic imaging of a patient's breast when used with an automatic scanning annular array transducer. Automatic scanning obtains multiple, sequential two-dimensional images which can be compiled into a three-dimensional data set for viewing in three planes. The system is intended to be used for the real-time ultrasonic guidance of needle aspiration and biopsy procedures of breast lesions.

The Sonopsy LA System is indicated for use for the diagnostic ultrasound B-mode imaging of small organs (breast, thyroid, testes) and the abdomen when used with the hand-held linear array scanhead.

Prescription Use   X    
(Per 21 CFR 801.109)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number   K980423

**Diagnostic Ultrasound Indications for Use Form**

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

Device: Sonopsy LA System

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

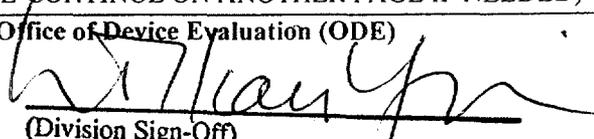
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional comments: Small organ: P = breast (K951999); N = thyroid, testes

Other: P = real-time biopsy guidance for breast lesions (K951999)

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

CONCURRENCE of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number K980423

Indications for Use  
 REVISED

**Diagnostic Ultrasound Indications for Use Form**

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

Device: 7.5 MHz Annular Array

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)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)		P								
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)		P								

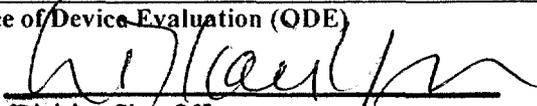
N = new indication; P = previously cleared by FDA; E = added under Appendix E

Additional comments: Small organ: P = breast (K951999)

Other: P = real-time biopsy guidance for breast lesions (K951999)

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

CONCURRENCE of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K980423

Prescription Use (Per 21 CFR 801.109)

Indications for Use  
 REVISED

**Diagnostic Ultrasound Indications for Use Form**

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

Device: 7.5/5.0 MHz Linear Array

Clinical application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		N								
Intraoperative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)		N								
Neonatal Cephalic										
Adult Cephalic										
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: Small Organ: N = breast, thyroid, testes

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

CONCURRENCE of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

Indications for Use  
 REVISED

510(k) Number K980423