

JUN 23 1999

PREMARKET NOTIFICATION [510(K)] SUMMARY

1. **Submitted by:** SRS International® Corporation
Suite 1000, 1625 K Street, NW
Washington, D.C. 20006
Telephone: 202-223-0157
Fax: 202-835-8970
2. **Contact Person:** Michael G. Farrow, Ph.D.
3. **Name of the Device**
 - a. **Trade Name:** Longport™ Model LDST™-1
 - b. **Common Name:** Ultrasound Scanner
 - c. **Classification Name:** Class II 90 IYO
System, Imaging, Pulsed Echo, Ultrasonic
4. **Legally Marketed Device for which we are claiming substantial equivalence:**

DermaScan C® ver. 3
Cortex Technology
Textilvaenget 1
9560 Hadsund, Denmark
Telephone 45-9857-4100
Fax 45-9857-2223

The USA Representative for DermaScan is:
cyberDERM, inc.
275 New Darlington Road
Media, PA 19063-5607
Telephone 610-544-7868

The 510(k) number for DermaScan is:
K89-4834

5. **Description of the Device:**

The Longport™ LDST™-1 is a proprietary, non-invasive medical device for performing ultrasound scanning of the upper layers of the dermis. It is a portable, high frequency (20 MHz) ultrasound device which captures and reproduces images of soft tissue up to 1.5 inches below the skin at a high resolution utilizing a laptop computer.

6. Intended Use of the Device: Current indication for use:

“high resolution ultrasound imaging”

7. Summary of Technological Characteristics compared to Predicate Device:

Technological characteristics of this device which are similar to those of the predicate include:

- a. Transducer type: focused, single element
- b. Transducer stand-off medium: water
- c. Water reservoir retention: membrane
- d. Operating system: windows
- e. Operator control: keyboard/ mouse
- f. Processor: Pentium
- g. Data format: digital
- h. Data Storage: Hard/ floppy disk
- i. Distance Measurement
- j. Split Screen Features
- k. Palettes: Gray scale and color

Technological characteristics of this device which are different than the predicate include:

- a. Transducer Center Frequency:
Longport 20MHz; Predicate 10, 20, 30 MHz
- b. Scan Rate:
Longport 1 scan/ second; Predicate up to 6 scans/ second
- c. Safety:
Longport: IEC 601-1 & EMI: EN55011, Class A
Predicate: IEC 601 & UL 544
- d. Power Requirements
Longport: 100-200 V, 50-60 Hz
Predicate 110/220 VAC +/- 20%
- e. Power Consumption:
Longport: 250 W
Predicate 350 W
- f. Operating Temperature and Humidity:
Longport 0-55°C; 10-90% rel. non-condensing
Predicate: 10-40°C; 5-95% non-condensing



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 1999

Longport, Inc.
c/o Michael G. Farrow, Ph.D.
Official Correspondent
SRS International Corporation
Suite 1000
1625 K Street, NW
Washington, DC 20006-1604

RE: K990238
Longport Model LDS-1 (Ultrasound Skin Scanner)
Regulatory Class: II
Product Code: 90 IYO 21 CFR 892.1560
Dated: June 10, 1999
Received: June 10, 1999

Dear Dr. Farrow:

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 Longport Model LDS-1, as described in your premarket notification:

Transducer Model Number
20 MHz Transducer

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:

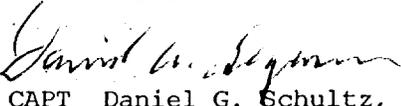
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for 

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K-99-0238

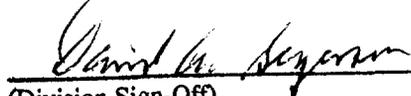
Device Name: ~~Longport Model LDS-1~~

Indications For Use:

high resolution ultrasound imaging

(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 K990238

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

LDS-1 Ultrasound System

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										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify) SKIN		N								

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

Additional Comments: Track 1

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Concurrence of CDRH; Office of Device Evaluation (ODE)

David A. Seaman
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

Prescription Use (Per 21 CFR 801.109)

20 MHz Transducer for use with the LDS-1 Ultrasound System 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)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify) SKIN		N								

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

Additional Comments: Track 1

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Beynon
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K990238