SUMMARY OF SAFETY AND EFFECTIVENESS

NOV - 5 1997

K973079

I. GENERAL INFORMATION

Device generic name: Ultrasonic pulsed echo imaging system and ultrasonic transducer

Device trade name: Aspen ultrasound system and L7 transducer

Applicants name: Acuson Corporation
1220 Charleston Road
Mountain View, CA 94043

510(k) No.: Unknown at this time

Date of 510(k) submission: August 15, 1997

II. INDICATIONS FOR USE

The L7 when used with Aspen ultrasound system is capable of providing diagnostically useful images of anatomy and pathology in the major bone, joint, and muscle groups of the human body. Specific anatomy and pathology in the neck, shoulders, arms, elbows, wrist, hand, hips and pelvis, legs, knees, ankles and feet can be imaged. The images obtained depict anatomical structures and regions of increased and reduced blood flow which are useful to physicians in detecting normal and abnormal conditions in these regions of the body.

III. DEVICE DESCRIPTION

The Aspen model ultrasound system and L7 transducer is a general purpose diagnostic ultrasound system that received marketing clearance via 510(k) K934915/S1 on October 21, 1994. For the musculoskeletal indication for use described above, the device consists of the L7, a 128 element, 3-10 Mhz broadband, 38 mm flat linear array transducer and electronic and mechanical hardware, software controls, and digital components comprising the ultrasound system console.

The maximum acoustic outputs for any musculoskeletal L7 operating mode are $I_{SPTA.3} = 86$ mW/cm^2 and $I_{SPPA.3} = 124$ W/cm^2. The L7 may be used for musculoskeletal imaging in the following operating modes: B mode, M mode. Color Doppler mode, and Pulsed Wave Doppler mode.

IV. WARNINGS AND PRECAUTIONS

The addition of the musculoskeletal indication for use did not result in the addition of new warnings or precautions to the user manuals.

V. POTENTIAL ADVERSE EFFECTS

Addition of the musculoskeletal indication for use did not introduce any new potential hazards to the use of the Aspen/L7 system. Since the introduction of the Aspen system in October, 1996, no adverse health effects to the patient and user population have been confirmed.

VI. BIOCOMPATIBILITY

No material changes to the L7 were necessary to add the musculoskeletal indication for use. Biocompatibility data for all Acuson transducer materials contacting patients is on file.

VII. IMAGING PERFORMANCE

Clinical studies were conducted to verify system performance in all imaging modes. Clinical data was submitted to the Food and Drug Administration as part of our 510(k) notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 1997

William E. Welch
Regulatory Affairs Manager
ACUSON Corp.
1220 Charleston Road
P.O. Box 7393
Mountain View, CA 94039-7393

Re: K973079
ACUSON Model L7 Transducer for
Model 2001 (Aspen) Ultrasound System
Dated: October 20, 1997
Received: October 21, 1997
Regulatory Class: II
21 CFR 892.1550/Procode: 90 IYN
21 CFR 892.1570/Procode: 90 ITX

Dear Mr. Welch:

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 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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Model 2001 (Aspen) Ultrasound System, as described in your premarket notification:

Transducer Model Number

ACUSON Model L7

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 February 17, 1993 "Revised 510(k) Diagnostic Ultrasound Guidance for 1993." 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,

for 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

Enclosure(s)

ATTACHMENT A
Ultrasound Device Indications Statement

Ultrasound System: - Aspen

Transducer: L7

Clinical Applications	A	B		PWD	CWD	Color Doppler	Power (Ampl.) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		x	x	x	x	x	x		*	
Intra-operative - abdominal - cardiac		x	x	x	x	x	x		*	
Intra-operative Neurological										
Pediatric										
Small Organ - Thyroid - Breast - Testicle		x	x	x	x	x	x		*	
Neonatal Cephalic		x	x	x	x	x	x		*	
Adult Cephalic										
Cardiac		x	x	x	x	x	x		*	
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular		x	x	x	x	x	x		*	
Laparoscopic										
Musculo-Skeletal Conventional		x	x	x	x	x	x		*	
Musculo-Skeletal Superficial		x	x	x	x	x	x		*	
Other (Specify)										

Additional Comments:

* Combinations: B+M, B+PWD, B+Color Doppler, B+PWD+Color Doppler, B+Power Doppler, B+PWD+Power Doppler,

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973079

Prescription Use _____
(Per 21 CFR 801.109)