K080176

510(k) Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92

FEB 29 2008

Section a):

1. Submitter: Aloka Co., Ltd., 10 Fairfield Boulevard, Wallingford, CT 06492

   Contact Person: Richard J. Cehovsky, RA/QA Coordinator,
   Tel: (203)269-5088 Ext. 346, Fax: 203-269-6075

   Date Prepared: 2/6/2008

2. Device Name: Aloka Prosound 6 Diagnostic Ultrasound System
   Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550 , 90 IYN
   Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90 ITX
   Ultrasonic Pulsed Echo Imaging System., 21 CFR 892.1560, 90 IYO

3. Marketed Device: Aloka SSD-1400 Diagnostic Ultrasound System K972465, (90-IYN, ITX,IYO)
   (A device currently in commercial distribution)

4. Device Description: The Aloka Prosound 6 Diagnostic Ultrasound System is a full feature imaging and analysis system. It consist of a mobile console that provides acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls and a video display.

5. Indications for Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal, Abdominal (including renal and GYN), Pediatric, Small Organ (breast, testes, thyroid), Neonatal Cephalic, Peripheral Vascular, Transrectal, Transvaginal and Intraoperative (abdominal, thoracic & vascular) applications. The device is not indicated for Ophthalmic applications.

6.Comparison w/ Predicate Device:
The Aloka Prosound 6 is technically comparable and substantially equivalent to the current Aloka SSD-1400-(K972465). It has the same technological characteristics, key safety and effectiveness features, physical design, construction, materials and has the same intended uses and basic operating modes as the predicate device.

Section b):

1. Non-clinical Tests: The device and its transducers have been evaluated for acoustic output, biocompatibility, cleaning & disinfection effectiveness, electromagnetic compatibility, as well as electrical and mechanical safety, and have been found to conform with applicable medical device safety standards.

2. Clinical Tests: None Required.

3. Conclusion: Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001:2000 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effectiveness performance. Therefore, it is the opinion of Aloka Co., Ltd. that the Aloka ProSound 6 Diagnostic Ultrasound System and its transducers is substantially equivalent with respect to safety and effectiveness to its predicate and other currently cleared Aloka systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 9 2008

Aloka Co., Ltd.
% Mr. Tamas Borsai
Division Manager, Medical Division
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K080176
Trade/Device Name: Aloka Prosound 6 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: February 13, 2008
Received: February 15, 2008

Dear Mr. Borsai:

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 Aloka Prosound 6 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

UST-672-5/7.5	UST-5413	UST-9124
UST-676P	UST-5542	UST-9127
UST-987-7.5	UST-5710-7.5	UST-9133
UST-995-7.5	UST-9102U-3.5	UST-MC11-8731
UST-5045P-3.5	UST-9123	

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 (240) 276-3150 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 Ms. Lauren Hefner at (240) 276-3666.

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)

Indications for Use

510(K) Number (if known): K080176

Device Name: Aloka Prosound 6

Indications For Use:

The device is intended for use by a qualified physician for ultrasound evaluation of Fetal, Abdominal (including renal and GYN), Pediatric, Small Organ (breast, testes, thyroid), Neonatal Cephalic, Peripheral Vascular, Transrectal, Transvaginal and Intraoperative (abdominal, thoracic & vascular) applications.

The device is not indicated for Ophthalmic applications.

Prescription Use ___√___ **AND/OR** **Over-The Counter Use**_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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, and Radiological Devices
510(k) Number K080176