K083254

DEC 19 2008

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

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: 9/18/08

2. Device Name: Aloka Prosound 2 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-500 Diagnostic Ultrasound System K900805, (90-IYN, ITX, IYO)
   (A device currently in commercial distribution)

4. Device Description: The Aloka Prosound 2 Diagnostic Ultrasound System is a light weight, full-digital portable imaging and analysis system. It consist of a high resolution LCD flat panel monitor that provides excellent image quality and processing . The user interface includes a computer type keyboard, specialized controls and a display.

5. Indications for Use: The device is intended for use by a qualified physician for ultrasound evaluation of Gyneological, Fetal, Peripheral Vascular, Cardiac, Neonatal Cephalic, Small Parts, Intra-operative, Transrectal and Abdominal applications. The device is not indicated for Ophthalmic applications.

6.Comparison w/ Predicate Device:
The Aloka Prosound 2 is technically comparable and substantially equivalent to the current Aloka SSD-500-(K900805). It has the same technological characteristics, key safety and effectiveness features, 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 2 Diagnostic Ultrasound System and its transducers are 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

DEC 19 2008

Aloka Co., Ltd
c/o Mr. Tamas Borsai
Division Manager, Medical Division
TÜV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K083254
Trade/Device Name: Aloka Prosound 2
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN
Dated: December 2, 2008
Received: December 4, 2008

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

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 letter will allow you to begin marketing your device as described in your Section 510(k) 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 the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): K083254

Device Name: Aloka Prosound 2

Indications For Use:

The device is intended for use by a qualified physician for ultrasound evaluation of Gyneological, Fetal, Peripheral Vascular, Cardiac, Neonatal Cephalic, Small Parts, Intra-operative, Transrectal and Abdominal applications.

The device is not indicated for Ophthalmic applications.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The Counter Use**_____ (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 K083254