K081843

JUL 15 2008

510(k) Summary

Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92

Date Prepared: 05/27/2008

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

2. Device Name:
   - Trade Name- DAS-RS1 (Ultrasound Data Analysis System),
   - Classification Name: Picture Archiving and Communication System,
   - Classification Panel: Radiology,
   - CFR Section: 21 CFR 892.2050,
   - Device Class: II,
   - Product Code: LLZ

3. Intended Use:
   The Aloka DAS-RS1 is intended to acquire, read, display, store and review DICOM image and data, including the ability to analyze and print reports primarily for Aloka diagnostic ultrasound systems.

4. Device Description:
   The Aloka DAS-RS1 system is a software based medical image system. This system receives, reviews and store patient exam images and data, prepare/print reports and communicates with Aloka Ultrasound systems. This system has a PC workstation that can be used to analyze the data for report generation. The software allows for the download of DICOM files to a single PC from a single Aloka Ultrasound system located within the same facility.

5. Substantial Equivalence:
   The Aloka DAS-RS1 is functionally comparable and substantially equivalent to the Philips Medical Systems QLAB Software (K021966). The DAS-RS1 has similar technological characteristics, key safety and effectiveness features and essentially the same intended use as the predicate device.

6. General Safety and Effectiveness

Section b):

1. Non-Clinical Tests:
   The DAS-RS1 has been evaluated for conformance to its design specifications and applicable industry standards for software development. Risk management is ensured via risk analysis which is used to identify potential hazards. The potential hazards are controlled via software development, verification and validation. It is further verified for system compatibility with the Aloka Ultrasound device that it communicates to. Computer hardware is certified to applicable safety standards.

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2. Clinical Tests:

None Required to confirm safety and effectiveness. However, evaluation in a clinical setting was performed to ensure usability, reliability, reliability and compatibility within the intended environment.

7. Summary Conclusion:

The design and development process of the manufacturer conforms to 21 CFR 820, ISO 9001:2000 and ISO 13485: 2003 quality systems. The device is DICOM compliant and conforms to applicable medical safety standards and compliance is verified through internal and independent quality system and test verification. Intended uses and other key features of the device are consistent with traditional clinical practice, FDA guidelines and established methods of handling patient examination images and data. PACS devices and medical information systems in general have demonstrated a history of effective performance. Therefore, it is the opinion of Aloka Co., Ltd. that the Aloka DAS-RS1 system is substantially equivalent with respect to safety and effectiveness to devices currently cleared market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2008

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

Re: K081843
Trade/Device Name: Aloka DAS-RS1 (Ultrasound Data Analysis System)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 26, 2008
Received: June 30, 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(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 Biometric's (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,

Nancy C Brogdon

Nancy C. Brogdon
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):

Device Name: **Aloka DAS-RS1 (Ultrasound Data Analysis System)**

Indications For Use:

The Aloka DAS-RS1 is intended to acquire, read, display, store and review DICOM image and data, including the ability to analyze and print reports primarily for Aloka diagnostic ultrasound systems.

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 K 081843

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