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MAY 20 1999

510(k) Summary
Life Imaging Systems L3Di

Submitter (Consultant) Name and Address

Morningstar Consulting Group, Inc.
P. O. Box 219
Indian Hills, CO 80454

Submitter (Consultant) Contact Person

Kevin Morningstar, Senior Consultant
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Manufacturer Name and Address

Life Imaging Systems, Inc.
Suite 300, 195 Dufferin Avenue
London, Ontario, Canada N6A 1K7

Manufacturer Contact Person

Tom Holbrook, Quality and Regulatory Affairs Manager
phone (519) 679-4319 ext. 217
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Common, Classification & Proprietary Names

Common Name:	Digital Ultrasound Image Analysis System
Classification Name:	System, Image Processing
Proprietary Name:	Life Imaging Systems L3Di

Predicate Device

Life Imaging Systems LIS 6000A
K961403

Device Description

The Life Imaging Systems L3Di is a high performance computer system based on Apple Computer and Windows NT standards. It incorporates a commercially

available image digitizer circuit board and proprietary software for the acquisition, analysis, storage and retrieval of digital 3D ultrasound image data sets. The device is an add-on accessory for any existing diagnostic imaging ultrasound system.

The device records ultrasound transducer spatial position during use, either with transducer positioner assemblies or with a 6-degree of freedom coordinate tracking system.

Intended Use

The Life Imaging Systems L3Di is indicated for acquisition of related sets of 2D ultrasound images and 3 dimensional reconstruction of diagnostic ultrasound images. It is intended to acquire, analyze, store and retrieve digital ultrasound images for computerized 3-dimensional image processing. It is an add-on accessory for existing ultrasound imaging systems, and is intended to record position and movement of ultrasound transducers for the systematic acquisition of 2 dimensional image slices throughout a volume of interest. It is intended as a general purpose digital 3D ultrasound image processing tool for radiology, neurology, gastroenterology, urology, surgery, orthopedics, oncology, cardiology, obstetrics and gynecology.

Technological Characteristics Comparison

The LIS L3Di is nearly identical in performance and intended use to the LIS 6000A. Both systems are based on Apple Computer architecture, with proprietary software added for ultrasound image acquisition, 3D reconstruction, analysis, archival and retrieval. Both systems are used in the same clinical setting. Both systems work with any existing diagnostic ultrasound imaging system.

Test Discussion

Testing was performed according to internal company procedures. Software testing and validation were done at the module and system level according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release. Additional system testing was done by a third party standards test house.

Test Conclusions

Test results support the conclusion that actual device performance satisfies the design intent. Actual device performance as tested internally and by a third party conforms to the system performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1999

Life Imaging Systems, Inc.
c/o Kevin Morningstar
Morningstar Consulting Group
P.O. Box 218
Indian Hills, Colorado 80454

Re: K990560
Life Imaging Systems L3 Di
Digital Ultrasound Image Analysis System
Dated: February 15, 1999
Received: February 22, 1999
Regulatory Class: II
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.1550/Procode: 90 IYN

Dear Mr. Morningstar:

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.

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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

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

510(k) Number (if known): K990560

Device Name: Life Imaging Systems L3Di

Indications for Use:

The Life Imaging Systems L3Di is indicated for acquisition of related sets of 2D ultrasound images and 3 dimensional reconstruction of diagnostic ultrasound images. It is intended to acquire, analyze, store and retrieve digital ultrasound images for computerized 3-dimensional image processing such as distance, area, volume and angle measurements. It is an add-on accessory for existing ultrasound imaging systems, and is intended to record position and movement of ultrasound transducers for the systematic acquisition of 2 dimensional image slices throughout a volume of interest. It is intended as a general purpose digital 3D ultrasound image processing tool for radiology, neurology, gastroenterology, urology, surgery, orthopedics, oncology, cardiology, obstetrics and gynecology.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990560

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)