K052610

SUMMARY

NOV 3 0 2005

510k Summary for "k052610" premarket notification
Submission for a TV camera and digital imaging processor

Lakeshore Technologies Inc., formally Syracuse Scientific Inc., is requesting approval to market its SS960 CCD TV camera in combination with its Image Star II digital image processor. We manufacture this product at 7536 Murray Dr. Cicero, NY 13039.

A) **Classification Name:** Image Star System
Common / usual name: Digital Image Processor System
Proprietary Name: Image Star II

B) **Establishment Registration number**: 9020592

C) **Classification**: Since our system becomes a component of a class two devise, we have considered it as a class two devise, but we are unaware of it's actual classification. This system is not subject to any performance standards. We do not manufacture the TV monitor, which is a class two devise, and we do not manufacture the x-ray machine to which our imaging system is connected. Our Fluorecord system which we are comparing our new system to has 510k number K952493, is a class 2 devise and the product code is JAA.

D) **Performance Standards**: Not applicable

E) **Label / Labeling / Advertisements**: Copies of the package labeling, operation manual, technical and installation instructions, and schematics are enclosed.

F) **Intended Use**: For the presentation of a Fluoroscopic or Radiographic TV image as presented by the image intensifier of the X-ray system. This is to be used in diagnostic radiology or cardiology. These images may also be used to assist in operative procedures.

G) **Substantial Equivalence**: This devise is similar to our Fluorecord Imaging System (510k)
K952493 in terms of the operation, design and intended use. A side by side comparison of specifications is enclosed.

SECTION: 1.1

General Description of the Image Star System

The Image Star II digital image processor in combination with the SS960 CCD TV camera makes up a simple, low cost, high performance imaging system. This system is designed to be used in place of the conventional 100mm or 105mm spot film cameras for any standard RF procedure. This digital imaging system will be used instead of, or in addition to, the standard spot film device. This system is designed to interface easily, in a generic manner, to any x-ray system that is designed to accommodate a spot rapid and /or cine camera. The SS960 CCD TV camera will present a flickerless image when interfaced to any x-ray generator performing pulsed fluoroscopy and/or cine radiography.

Image Star II is a complete digital imaging system and is comprised of two main components; a main acquisition control unit or Work Station and a Review Station. Images are acquired, processed, displayed and reviewed to allow high quality image analysis and diagnosis with the following special features: Image Analysis, Image Processing, Exams storage, CD Recording, Intranet Server and Medical Report Editing. This system performs functions such as edge enhancement, noise reduction, multi frame loop, and digital subtraction. This makes it useful for diagnostic radiology, cardiology, urology, or mobile C-arm use.

The Work Station is interfaced to the x-ray generator and TV camera and is primarily used for acquisition. The Review Station is an optional independent Station connected to the Work Station through a high speed network and is primarily used for storage and review. Recorded images can be reviewed on both the Work Station and the Review Station. Studies can be opened, edited, analyzed, saved to a medical report and printed. Current or past patient studies can be viewed. Recorded images or image sequences can be zoomed, the window and level adjusted, annotation added and many other features. Patient data can be added, edited or deleted prior to the actual date and time of the exam. Patient data and information from a recorded study can be easily viewed. A full data redundancy system is used to store and maintain study data to eliminate loss or damage. Interfacing to the Work Station and Review Station is accomplished with the use of a standard text keyboard and mouse. An optional Touch Screen can also be used to interface with the Graphics User Interface.

The camera is a two piece configuration including a camera head and a camera control unit (CCU). The camera head is a single board design utilizing a single flexible interconnecting cable for power and low voltage digital signal (LVDS) output to the CCU. The CCU has both standard video outputs such as 1049/60 Hz interlaced or XVGA and also an LVDS digital output to the Image Star image processor.

This system is DICOM 3.0 compliant for interfacing to a DICOM network and can be connected to paper printers for generating medical report documents.

SECTION: 2.2

Brochures on Predicate Device

The following pages are brochures of the Fluorecord imaging system.

510(k) Number	K952493
Devise Name	FLUORECORD MODEL 762
Product Code	JAA
Decision Date	06/22/1995
Decision	Substantially Equivalent (SE)

SECTION: 4.1

Software Considerations

Our system is mainly intended for presenting a high quality TV image for the purpose of diagnoses or to assist in operative procedures. These TV images are stored to the hard disks redundantly by both of the system computers. The TV images may then be transferred to film by a video camera or laser imager or saved to an archival system via the DICOM network. We do have software in this system for performing measurements and quantitative analysis and the method used to derive these measurements are based on established techniques. (Refer to Section 4.4 for the methods used for these measurements).

The software in the system is in the form of executable files that run on the Windows XP* operating system platform. This software is used for the following purposes.

1) Control of entering patient identification and hospital identification and displaying this information on the TV monitor.
2) Control of transferring image data to and from the disk storage system and to a laser imager, video camera device or DICOM network.
3) Control of image processing circuitry for enhancement of image quality. Such as, edge enhancement, noise reduction etc.
4) Control for acting upon operator input from the keyboard or mouse.

The software control in the system has a **minor level** of concern in terms of patient safety. It is extremely unlikely for a failure to occur having an effect on the TV image that would produce an artifact that could be mistaken for a patient anomaly. All conceivable failures in our validation procedures would produce an obvious (problem) image.

We have displayed the patient name on the TV monitor in order to protect from images being stored with the incorrect patient identification. Our philosophy is that we cannot protect from an operator error in terms of entering the wrong information. Therefore, the information is displayed so that the entire staff in the procedure room can see the patient identification on the monitor to allow someone to point out an error.

We have taken additional precaution to protect the patient identification and image data that represents the patient's medical document files in two ways. First, all TV images are stored to hard disk redundantly on both the work station and the review station computers. Secondly, in many systems when the hard disks are full, the oldest exams are deleted or overwritten automatically to make room for the newer exams. In this system, the oldest TV images can only be deleted after being saved on the DICOM network or CD / DVD media and only with direct intervention by the user.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Jack Race
Lakeshore Technologies, Inc.
Formerly Syracuse Scientific, Inc.
7536 Murray Drive
CICERO NY 13039

AUG 21 2013

Re: K052610
Trade/Device Name: Image Star II
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: November 8, 2005
Received: November 10, 2005

Dear Mr. Race:

This letter corrects our substantially equivalent letter of November 30, 2005.

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): __k052610_____

Device Name: ___Image Star System_____

Indications for Use:

Lakeshore Technologies Inc., formally Syracuse Scientific Inc., intends to use its SS960 CCD TV camera in combination with its Image Star II digital image processor for the presentation of Fluoroscopic or Radiographic TV images as presented by the image intensifier of the X-ray system.

A) The images may also be used to assist in operative procedures.

B) This device is to be used in diagnostic radiology or cardiology.

C) The clinical settings for this device are hospitals and /or medical centers.

D) This device is to be used by a qualified radiologist or cardiologist.

E) This device is substantial equivalent to our Fluorecord Imaging System (510k k952493) in terms of the operation, design and intended use.

David A. Jegerson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052610

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)