K013841

JAN 1 7 2002

3DSharp Inc. 6425 Forward Ave. Pittsburgh, PA 15217 (412)648-9211

510(k) Summary

Description

The 3DSharp Fluoroscope Image System (**3DFIS** - Model IES-FL-101) is a stand-alone computer display system interfaced to a fluoroscope through a video cable. The images produced by the fluoroscope are transmitted through the cable to a frame capture board in the computer where the images are enhanced and then displayed on the computer's monitor. Each image is displayed on the **3DFIS** monitor at the same time as the corresponding original image is displayed on the fluoroscope monitor(s).

The 3DSharp Fluoroscope Image System **3DFIS** is designed for use in conjunction with any fluoroscope which has a video output connection. The use of the device enables contrast and brightness enhancement with simultaneous reduction of random noise.

The enclosure for the **3DFIS** is metal (aluminum). The other components are commercially available hardware and electronic components.

Intended Use

The **3DFIS** is intended for use in any application where a fluoroscope is incorporated to aid in diagnosis and treatment of desease.

Technological Characteristics

The 3DSharp Fluoroscope Image System (**3DFIS**) is designed as a "retrofit" for an existing fluoroscope. Its use provides improved image enhancement capabilities in addition to those provided by the fluoroscope. The **3DFIS** is connected to the fluoroscope by a video cable.

The **3DFIS** is comprised of three elements. The input element to which the video images from the fluoroscope are transmitted is a video frame capture interface. The computational element, the central component of the system, is a computer. The computer includes several expansion bus slots, two of which house the frame capture card and the display interface. The third element is the **3DFIS** display.

The **3DFIS** software controls the frame capture, intermediate image manipulation, and subsequent image display on the **3DFIS** monitor. Three image manipulation modes are provided. These are user selectable using a foot pedal, hand control or via the computer keyboard. These modes are:

- **RAW**: The images are unmodified.
- **AVG**: A contiguous sequence of images is averaged together.
- **LIT**: These images are modified using the **3DSharp** image enhancement method.

Performance

The **3DFIS** processes images at any user selectable rate up to full frame rate (30 frames/sec). The delay between frame acquisition and frame display is less than the time between frames, i.e. 33 msec. Utilization of the **3DFIS** in the **AVG** or **LIT** modes produces enhanced image contrast and reduced image noise.

Safety and Effectiveness

The device serves only as an image display which is in addition to the fluoroscope's standard image display device. Both are viewable at all times. Furthermore, the device is passive, i.e. its operation depends only on the video output of the fluoroscope. Neither control signals or images move in the other direction from the **3DFIS** to the fluoroscope. It herefore has no adverse safety or effectiveness issues and its use poses no risk of injury or death to patient or medical personnel.

The electronic components of the **3DFIS**, i.e. the Apple Corp. PowerMac computer and the Scion Corp. CG7 frame grabber, have been tested by their manufacturers and have been found to comply with the limits for a Class B digital device in accordance with the specification in Part 15 of FCC rules. In addition, the PowerMac computer is U.S. EPA ENERGY STAR compliant and is TCO95 approved and labelled. The TCO standard covers environmental issues, ergonomics, usability, reduction of electric and magnetic fields, energy consumption, and energy safety. The **3DFIS** monitor has the following agency approvals: FCC Part 15 Class B, EN55022 Class B, EN55024, VCCI Class 2B, AS/NZS 3548 Class B, CNS 13438 Class B, ICES-003 Class B, MPR II, EC 950, UL 1950, CSA 950, EN60950, U.S. EPA ENERGY STAR, TCO 95.

Classification

The 3DFIS is classified as "System, Image Processing." It is equivalent in safety and performance to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2002

Don Krieger, Ph.D.
3DSharp, Inc.
6425 Forward Ave.
PITTSBURG PA 15217

Re: K013841
Trade/Device Name: 3DSharp Fluoroscope Image System Model IES-FL-101
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: November 19, 2001
Received: November 20, 2001

Dear Dr. Krieger:

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 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

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

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510(k) Number (if known): K013841

Device Name: 3DSharp Fluoroscope Image System (3DFIS) Model IES-FL-101

Indications For Use:

The 3DFIS is intended for use in any application where a fluoroscope is incorporated to aid in diagnosis and treatment of disease.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013841