

JAN 7 1999

K983567

510(k) Summary
Image Technologies Corporation
SteriCam, Coupler-Drape and TroView System

1. SPONSOR

Image Technologies Corporation
27 Wormwood Street
Boston, MA 02210-1625
Telephone: 617-428-7595
Facsimile: 617-428-7599

Contact Person: Lunn Sawyer

Date Prepared: October 9, 1998

2. DEVICE NAME

Classification Name: Endoscopes and accessories, 21 CFR 876.1500
Proprietary Name: TroCam/TroView Endoscopy System

3. INTENDED USE

The Image Technologies Corporation's SteriCam, Coupler-Drape and TroView Imaging System consists of a CCD camera, coupler and a computer-based documentation system. The SteriCam is intended to attach to a standard commercially available endoscope for visualization of body cavities, hollow organs, and canals. The SteriCam Coupler is intended to couple the SteriCam to the standard commercially available endoscope. The TroView System is intended to provide documentation/storage of the image in the field of view of the SteriCam camera.

4. DEVICE DESCRIPTION

The Image Technologies Corporation's SteriCam, SteriCam Coupler-Drape and TroView Imaging System consists of a CCD camera, coupler and a computer based documentation system. The SteriCam takes the image that normally would be seen by the naked eye, and displays it on a color monitor. The SteriCam provides

imaging through standard commercially available endoscopes and is designed to be used with the sterile SteriCam Coupler-Drape. The Coupler-Drape includes a sterile drape component. The SteriCam is placed within the sterile drape of the Coupler-Drape to prevent contamination in the sterile field. The video signal cable connects the SteriCam to the TroView Documentation System.

The SteriCam Coupler-Drape's distal end attaches to the eyepiece of a conventional endoscope and uses the SteriCam CCD camera to display the image on the computer monitor. The SteriCam Coupler-Drape simply connects the conventional endoscope to the SteriCam. The SteriCam Coupler-Drape is sterile and includes the drape so that the non-sterile SteriCam Camera and cable are covered during the surgical procedures. Although the SteriCam Coupler-Drape attaches to various endoscopes, it is designed to be used only with the SteriCam camera.

The TroView System is a non-sterile reusable unit that is intended to provide real time image displays as well as storage of the image in the field of view of the SteriCam. As the TroView receives and displays the SteriCam digitized video output, the images can be adjusted for brightness, hue, contrast and saturation. The TroView System allows for printing to a dedicated printer or saving the image in to a 1.44 MB 3.5" floppy disk or other storage medium. A software based zoom is also permitted.

A sterile disposable Remote Controller is also offered with the TroView System which permits remote control access to key camera and computer functions. The Remote Controller looks and performs identically to the controller pad located on the faceplate of the computer. The physician is able to place the sterile Remote Controller in the sterile field whereas the faceplate of the computer is non-sterile and situated outside the sterile field.

5. PERFORMANCE TESTING

Image Quality testing was performed on the SteriCam, Coupler-Drape, and TroView System using the USAF 1951 Test Target designed to MIL-STD-150. The results showed that the TroView System resulted in a resolution of 3.17 lines per mm, which is comparable to that of the predicate devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mary McNamara-Cullinane, RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K983567
Trade Name: Image Technologies SteriCam, Coupler-Drape and TroView Imaging System
Regulatory Class: II
Product Code: GCJ
Dated: October 9, 1998
Received: October 13, 1998

Dear Ms. McNamara-Cullinane:

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 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.

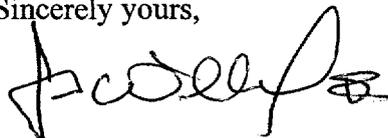
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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.

Page 2 – Ms. Mary McNamara-Cullinane, RAC

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) 594-4595. 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/dsmamain.html>".

Sincerely yours,


Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): V983567

Device Name: Image Technologies SteriCam, Coupler-Drape and TroView Imaging System

Indications For Use:

The Image Technologies Corporation SteriCam and TroView Imaging System consists of a CCD camera, coupler and a computer-based documentation system. The SteriCam is intended to attach to a standard commercially available endoscope for visualization of body cavities, hollow organs, and canals. The System includes a Coupler-Drape Assembly which is intended to couple the SteriCam to a standard commercially available endoscope. The TroView System is intended to provide documentation/storage of the image in the field of view of the SteriCam.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

[Signature]
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K983567