

JUL 20 1999

510(k) Summary
for
Genzyme Surgical Products
Digital RGB and 3-Chip Digital RGB Endoscopic Cameras

K991416

1. SPONSOR

Genzyme Surgical Products Corporation
5175 South Royal Atlanta Drive
Tucker, GA 30084

Contact Person: Michelle Johnston
Telephone: 770-723-2725

Date Prepared: April 21, 1999

2. DEVICE NAME

Proprietary Name: Endoscopic Camera
Common/Usual Name: Endoscopic Camera
Classification Name: Accessory to an Endoscope

3. PREDICATE DEVICES

- Circon Corporation
MicroDigital Camera and DirectCoupler
K914883
- Karl Storz
EndoVision XL Endoscopic Camera System
K974391
- Karl Storz
EndoVision Digivideo System
K950974

4. DEVICE DESCRIPTION

The Genzyme Surgical Products Digital RGB and 3-Chip Digital RGB Endoscopic Cameras are designed to provide a picture of the surgical field during endoscopic procedures. The Digital RGB and 3-Chip Digital RGB Endoscopic Cameras take the image that would be normally seen by the naked eye, and displays it on a color monitor. The Digital RGB and 3-Chip Digital RGB Endoscopic Cameras provide imaging through standard, commercially available, legally marketed endoscopes.

The Digital RGB and the 3-Chip Digital RGB Endoscopic Cameras both consist of a Camera head, camera control box, and camera cable, camera cable connector soaking cap and coupler accessories. A coupler couples the camera head to the commercially available endoscope.

5. INTENDED USE

The Genzyme Surgical Products Digital RGB and 3-Chip Digital RGB Endoscopic Cameras are intended to attach to standard commercially available endoscopes for visualization of body cavities, hollow organs, and canals.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Genzyme Surgical Products Digital RGB and 3-Chip Digital RGB Endoscopic Cameras and the predicate devices are all intended to permit visualization of body cavities, hollow organs and canals. The Genzyme Surgical Products Camera components and the predicate devices are designed to be attached to commercially available endoscopes. The endoscopic image in the proposed and predicate devices can be displayed on any standard operating monitor or stored. A VCR/Video Printer can be used to produce hard copies of images obtained using both the proposed and predicate devices.

Both the Digital RGB and the 3-Chip Digital RGB Endoscopic Cameras and the Karl Storz EndoVision Digivideo System provide contrast enhancement and edge correction and are used in conjunction with cameras attached to rigid or flexible endoscopes.

7. PERFORMANCE TESTING

The devices were tested to EN 55011:03.1991 and EN 60601-1-2:05.1993.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 20 1999

Genzyme Surgical Products, Inc.
c/o Ms. Mary McNamara-Cullinane
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K991416
Trade Name: 3-Chip Digital RGB Video Camera
Regulatory Class: II
Product Code: GCJ
Dated: April 21, 1999
Received: April 23, 1999

Dear Ms. McNamara-Cullinane:

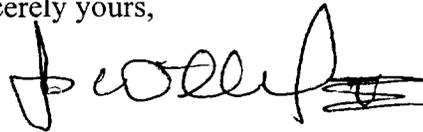
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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): K 991416

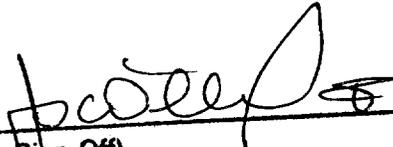
Device Name: Genzyme Surgical Products

Indications For Use:

The Digital RGB and 3-Chip Digital RGB Endoscopic Cameras are intended to attach to standard commercially available endoscopes for visualization of body cavities, hollow organs, and canals.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991416

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)