

APR 24 1998

510(k) SUMMARY
FOR
SONY DXC-LS1 COLOR VIDEO CAMERA

K980279

1. Applicant:

Sony Medical Systems Division
Sony Electronics Inc.
1 Sony Drive
Park Ridge, NJ 07656

Contact Person: Anthony John Kefalos
Telephone: 201-358-4330

Date Prepared: January 22, 1998

2. Device Name

Proprietary Name: Sony DXC-LS1 Color Video Camera
Common/Usual Name: Color Video Camera
Classification Status: Surgical Camera and Accessories; and Dental
Operative Unit and Accessories

3. Predicate Devices

Sony DXC-750MD Color Video Camera
Sony Medical Systems Division
K884343

Sony DXC-101/102 Series Color Video Camera
Sony Medical Systems Division
K884343

4. Device Description

The Sony DXC-LS1 is a progression in the DXC line of cameras. The DXC-LS1 is designed specifically for applications where space is limited. A comprehensive system of adaptors, lenses, cables and other accessories is available. These

accessories enable the camera to be used in various medical applications including surgery, microsurgery, endoscopy, dentistry and microscopy, and other general medical procedures involving reproduction of video images.

5. Intended Use

The Sony DXC-LS1 Color Video Camera is intended for use in capturing video images for display and storage in applications such as surgery, microsurgery, endoscopy, dentistry and microscopy.

6. Technological Characteristics

The DXC-LS1 Color Video Camera is intended as an addition to the Sony video camera product line. The DXC-LS1 has the same general purpose and function as the predicate devices identified above. These cameras are intended to be used to capture medical images for display, recording and printing. The primary difference between the Sony DXC-LS1 Color Video Camera and the substantially equivalent devices is the higher resolution and smaller size for use where space is critical. Also, the Charge-Coupled Device (CCD) image sensors used in the DXC-LS1 employ the Hyper HAD technology.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 24 1998

Ms. Cynthia A. Sinclair
Senior Staff Consultant
Sony Medical Electronics Company
c/o Medical Device Consultant, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K980279
Trade Name: Sony DXC-LS1 Color Video Camera
Regulatory Class: II
Product Code: GCJ
Dated: January 22, 1998
Received: January 26, 1998

Dear Ms. Sinclair:

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.

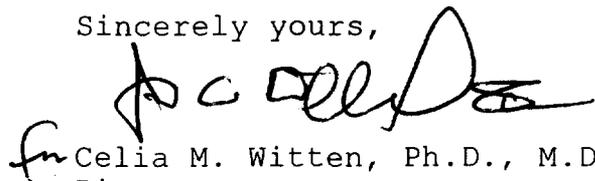
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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,



fn 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): K980279

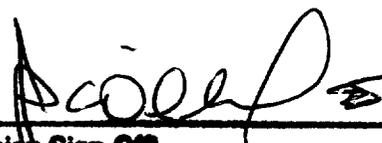
Device Name: Sony DXC-LS1 Color Video Camera

Indications For Use:

The Sony DXC-LS1 Color Video Camera is intended for use in capturing video images for display and storage in applications such as surgery, microsurgery, endoscopy, dentistry and microscopy.

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 K980279

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____