K971416

510 (k) SUMMARY
OLYMPUS OTV-S5C VIDEO SYSTEM

JUL 16 1997

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR, Section 807.92.

Device Name: Olympus OTV-S5C Video System, its associated accessories and ancillary equipment for CF application.

Common/Usual Name: Video Camera System

Classification Name: 21 CFR 876.1500, Class II
Endoscope and Accessories

Predicate Devices: Olympus OTV-S5 Video System, its associated accessories and ancillary equipment (BF Type).
Cleared in 510(k) # K955404.

Prepared & Submitted By: (Contact Person)
Mr. Subhash Patel
Olympus America Inc.
Endoscope Division
Two Corporate Center Drive
Melville, New York 11747-3157
(516) 844-5481

Summary Preparation Date: 4/10/97 [Revised - 7/15/97]

Statement of Intended Use:

A3908 Light Guide Cable

Olympus Light Guide Cable A3908 is intended for use in conjunction with Olympus OTV-S5C Video System and accessories with optical endoscopes for observation and recording during diagnostic and therapeutic applications requiring Type CF equipment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 1997

Mr. Subhash R. Patel
Regulatory Affairs Associate
Endoscope Division
Olympus America, Inc.
Two Corporate Center Drive
Melville, New York 11747-3157

Re: K971416
Olympus Light Cable Guide A3098 for use with
OES OTV-S5C Video System
Dated: April 10, 1997
Received: April 16, 1997
Regulatory class: II
21 CFR §876.1500/Product code: 78 KOG, GCJ

Dear Mr. Patel:

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) 594-4613. 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K971416

Device Name: Olympus OES OTV-S5C Video System, its associated accessories and ancillary equipment for CF applications.

Indications for Use:

A3908 Light Guide Cable

Olympus Light Guide Cable A3908 is intended for use in conjunction with Olympus OTV-S5C Video System and accessories with optical endoscopes for observation and recording during diagnostic and therapeutic applications requiring Type CF equipment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Ratliff
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT and Radiological Devices
510(k) Number K971416

Prescription Use ✓ OR Over-the Counter Use _____
(per 21CFR 801.109) (Optional Format 1-2-96)