K971328

JUL - 1 1997

510 (k) SUMMARY
OLYMPUS CD-6C-1 ELECTROSURGICAL SYSTEM

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 CD-6C-1 Coagulation Electrode.
Common/Usual Name:	Coagulation Electrodes
Classification Name:	21 CFR 876.4300, Class II Endoscopic Coagulation Electrode and Accessories.
Predicate Devices:	Olympus CD-1L/U Coagulation Electrode (Preamendment) Olympus KD Series Sphinctertomes (K955247)
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:	04/07/97

Statement of Intended Use:

Olympus CD-6C-1 Coagulation Electrode has been designed to be used with the Olympus BF-240 Bronchovideoscopes for electrosurgical cauterization or hemostasis in upper airways and tracheobronchial tree.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUL - 1 1997

Re: K971328
Trade Name: Olympus CD-6C-1 Coagulation Electrode
Regulatory Class: II
Product Code: FFE
Dated: April 7, 1997
Received: April 10, 1997

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.

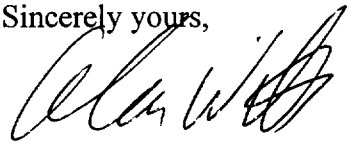
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Indications for Use Statement

510(k) Number (if known): Not assigned yet K971328

Device Name: Olympus CD-6C-1 Coagulation Electrode.

Indications for Use:

Olympus CD-6C-1 Coagulation Electrode has been designed to be used with the Olympus BF-240 Bronchovideoscopes for electrosurgical cauterization or hemostasis in upper airways and tracheobronchial tree.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971328