510 (k) SUMMARY

FOR OLYMPUS ENDOSCOPIC VIDEO INFORMATION SYSTEM

Device Name:	Olympus Endoscopic Video Information System/EVIS 200 (EVIS 200)
Common/Usual Name:	EVIS 200 (EVIS 200)
Classification Name:	Bronchoscope and Accessories
Predicate Devices:	Olympus EVS-Endoscopic Video Image and Data System (EVS), E-GIF Videoendoscope, E-JF Videoendoscope, E-CF Videoendoscope, EVS Video Processor, BF-N20 Bronchofiberscope, BF-B2, BF-5B Bronchofiberscope, BF-1T Bronchofiberscope, BF-4C2 Bronchofiberscope, BF-3C2 Bronchofiberscope, Disposable Biopsy Valve and Disposable Suction Valve.
Submitted By: **(Contact Person)**	Mr. Barry Sands Olympus Corporation Medical Instrument Division 4 Nevada Drive Lake Success, NY 11042 (516) 488-3880
Summary Preparation Date:	March 4, 1993

Statement of Intended Use

The intended use of this system is for the endoscopic diagnosis and treatment in the airways including the tracheobronchial tree.

Comparison to Predicate Devices

The Olympus EVIS 200 System is similar in design, function and intended use to currently marketed, Olympus EVS-Endoscopic Video Image and Data System (EVS), E-GIF Videoendoscope, E-JF Videoendoscope, E-CF Videoendoscope, EVS Video Processor, BF-N20 Bronchofiberscope, BF-B2, BF-5B Bronchofiberscope, BF-1T Bronchofiberscope, BF-4C2 Bronchofiberscope, BF-3C2 Bronchofiberscope, Disposable Biopsy Valve and Disposable Suction Valve.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

OCT - 7 1993

Barry E. Sands
Regulatory Affairs Manager
Research & Development
Olympus Corporation
Medical Instrument Division
4 Nevada Drive
Lake Success, New York 11042-1179

Re: K931154
Olympus EVIS 200 System
Videobronchoscope
Dated: March 5 and August 19,1993
Received: March 8 and August 23, 1993
Regulatory Class: I
21 CFR 874.4680

Dear Mr. Sands:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). General controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, 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. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence for your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326), at (301) 594-4639. 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 at (301) 443-6597.

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