

K 963033

**510 (k) SUMMARY  
OLYMPUS BF Type 240 BRONCHOVIDEOSCOPES**

SEP - 9 1996

**Device Name:** Olympus BF Type 240 Bronchovideoscopes, its associated and ancillary equipment and endoscopic accessories

**Common/Usual Name:** Bronchovideoscope and Accessories

**Classification Name:** Bronchoscope and Accessories

**Predicate Devices:** Olympus EVIS 200 System - Bronchoscopy (K931154)

**Submitted By:  
(Contact Person)** Mr. Barry E. Sands  
Olympus America Inc.  
Endoscope Division  
Two Corporate Center Drive  
Melville, New York 11747-3157  
(516) 844-5481

**Summary Preparation Date:** July 26, 1996

**Statement of Intended Use**

**BF Type 240 VIDEOBRONCHOSCOPES**

The BF Type 240 Bronchovideoscopes have been designed to be used with an Olympus EVIS CV- 200 video system center, light source, documentation equipment, video monitor, Endo-Therapy accessories, electrocautery devices, electrosurgical unit, and other ancillary equipment for endoscopic diagnosis and treatment within the airways and tracheobronchial tree.

**ENDOSCOPIC ANCILLARY EQUIPMENT AND ACCESSORIES**

All standard set and recommended accessories and equipment submitted in this submission are compatible and should be used with the subject BF 240 Type Bronchovideoscopes. Please refer to Subsection III-A for a copy of the Instruction Manual.

**Statement of Indications for Use**

The BF Type 240 Bronchovideoscopes have been specifically designed to be used with the recommended electrocautery devices for endoscopic diagnosis and treatment within the airways and tracheobronchial tree.

**Device Description**

Olympus offers three models: BF-240, BF-P240, and BF-1T240 of Bronchovideoscopes. They are specifically designed to be used in conjunction with the EVIS 200 Video System which was cleared in 510(k) # K931154 and recommended electrocautery devices.

All other characteristics such as optical, product specifications, material, intended use, and indications for use of the BF-240 Bronchovideoscopes remains unchanged except the modifications identified earlier in this section.

Olympus currently markets EVIS BF Type 200 Bronchovideoscopes, its associated accessories and ancillary equipment, which were cleared for marketing in 510(k) # K931154. The BF Type 240 Bronchovideoscopes are substantially equivalent to the BF Type 200 Bronchovideoscopes in design, specifications, materials, intended use, and method of use except the BF-240 allows the user to use the electrocautery devices such as electrosurgical snares and coagulation electrodes during the endoscopic procedure.

**General Safety**

The Olympus BF Type 240 Bronchovideoscopes are designed, manufactured and tested according to Voluntary Safety Standards IEC 601-1 and IEC 601-2-18.

When compared with the predicate devices, Olympus BF Type 240 Bronchovideoscopes do not incorporate any significant change in intended use, method of operation, material, or design that could affect the safety or effectiveness.