

AUG - 9 1996

K962380

**510 (k) SUMMARY**

**OLYMPUS EVIS 200 VIDEO ENDOSCOPY SYSTEM**

**Device Name:** Olympus EVIS BF 200 Series Video Bronchoscopes, it's associated accessories and ancillary equipment

**Common/Usual Name:** Video Bronchoscopes

**Classification Name:** Bronchoscopes and Accessories

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

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**Statement of Intended Use**

The Olympus EVIS BF Type 200 Series video bronchoscopes have been designed for endoscopic diagnosis and treatment within the airways, including the tracheobronchial tree.

**Device Description**

Olympus intends to offer three modified BF-200, BF-P200, and BF-1T200 models of video bronchoscopes to be used in conjunction with the EVIS 200 video system center. These video bronchoscopes are identical to the legally marketed video bronchoscopes, which were cleared for marketing through 510(k) # K931154, except for the insertion tube's outer coating material.

All characteristics such as design, construction, optical characteristics, mechanical specifications, electrical and thermal characteristics, intended use, method of use, and application sites remains unchanged.