

### 510 (k) SUMMARY

## OLYMPUS EVIS 140 VIDEO ENDOSCOPY SYSTEM

**Device Name:** Olympus EVIS 140 System, associated endoscope, and ancillary equipment and endoscopic accessories

**Common/Usual Name:** Olympus EVIS 140 System

**Classification Name:** Endoscope and Accessories

**Predicate Devices:** Olympus EVS Video Endoscopy System (K853585)  
Olympus EVIS 200 System - Bronchoscopy (K931154)  
Refer to Subsection I-A for additional list of predicate devices.

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#### Statement of Intended Use

The EVIS 140 System is specifically designed for endoscopic diagnosis, treatment, and photo and video documentation in combination with Olympus endoscopes, various accessories and ancillary equipment within the upper and lower digestive tract including esophagus, stomach, pancreatic duct, biliary duct, duodenum, small intestine, rectum and colon.

The intended use of EVIS 140 System and associated endoscopes are identical to the currently marketed EVS System which was cleared for marketing in the 510(k) # K853585. Both systems are used for observation, photo and video documentation of the images within the upper and lower GI tract. Thus, when compared to the predicate device, Olympus EVIS 140 System does not raise any questions regarding the safety of the subject device.