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510(K) SUMMARY

DEVICE: FG-36UX, FIBER ULTRASOUND UPPER GI GASTROSCOPE K961974

SUBMITTER INFORMATION:

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NAME OF DEVICE:

Common Name:	Ultrasound Fiber Gastroscope
Trade Name:	FG-36UX, Ultrasound Upper GI Fiberscope
Classification Name:	Diagnostic Ultrasound Transducer (74JOP) {892.1570}
	Endoscope and Accessories (78KOG) {876.1500}

PREDICATED DEVICE(S) INFORMATION:

FG-32UA, Ultrasound Upper GI Fiberscope		
With Hitachi Scanner EUB: 410, 450, 515, 565	Pentax	K904573
With Hitachi Scanner EUB 555	Penatx	K953876
FD-32A, Fiber Duodenoscope	Pentax	K812810
EUB-405, Ultrasound Scanner	Hitachi	K924126

DEVICE DESCRIPTION:

The FG-36UX Ultrasound Fiber Gastroscope, can be used with any Endoscopic Light Source (with the appropriate lightguide receptacle) and Hitachi Ultrasound Scanners (models EUB-405, -515, -555). The instrument has a flexible insertion tube (for entry into the body cavity), a control body, and umbilicus. The Umbilicus is bifurcated where one connector is connected to the light source and the other is connected a the Ultrasound Scanner. The control body includes controls for up/ down and left right angulation, accessory elevator, air/ water delivery, suction control, a biopsy inlet port, ultrasound balloon inflation port, and the viewing ocular. The device contains light carrying bundles, one to illuminate the body cavity, another to optically visualize anatomy. The instrument also contains a working channel through which biopsy devices, or other accessories, may be introduced (the instrument is supplied with two biopsy forceps). A convex linear array all electronic transducer is mounted in the distal tip of the insertion tube. The instrument is completely immersable (with the use of supplied cleaning accessories).

INTENDED USE:

The FG-36UX, Ultrasound Fiber Gastroscope, is intended to provide optical and sonographic visualization of, and therapeutic access to, the Upper Gastrointestinal Tract. The Upper GI Gastrointestinal Tract includes, but is not limited to, the organs; tissues; and subsystems: Esophagus, Stomach, Duodenum, Small Bowel, and underlying areas. The instrument is introduced per orally when the indications consistent with the requirement for procedure(s) are observed in Adult and Pediatric patient populations.

COMPARISON TO PREDICATED DEVICE(S):

The submission for substantial equivalence included design validation and verification data, certifications, and references to the predicate device submission. The submission for substantial equivalence was not based on an assessment of clinical performance data.