FEB - 7 1997

ATTACHMENT I

510(K) SUMMARY K963023

OLYMPUS GF TYPE UM30P ULTRASONIC ENDOSCOPE

Device Name: Olympus GF-UM30P Ultrasonic Endoscope
and related ancillary equipment

Common/Usual Name: Olympus Ultrasonic Endoscopes

Classification Name: Endoscope and Accessories

Predicate Devices: GF/JF/CF-UM20 (K926514)

Submitted By:
(Contact Person)
Mr. Subhash Patel
Olympus America Inc.
Regulatory Affairs
2 Corporate Center Drive
Melville, NY 11747
(516) 844-5481

Summary Preparation Date: January 27, 1997 (revised)

Statement of Intended Use:

The Olympus GF-UM30P Ultrasonic Endoscope is intended to be used in combination with the Ultrasound System, EU-M20 or EU-M30, for endoscopic ultrasound imaging of the gastrointestinal tract wall, billiary and pancreatic duct, and surrounding organs. This instrument also provide for Endoscopic Ultrasound (EUS) guided fine needle aspiration (FNA) to acquire submucosal tissue.

Device Descripton
In examining the GI tract, endoscopic ultrasound may be indicated. The conventional type ultrasound endoscope does not provide the capability for ultrasonic guidance of endoscopic accessories (i.e. biopsy forceps, aspiration biopsy needles, etc.) The mechanically radially scanning GF-UM30P ultrasound endoscope provides this capability since the direction of the sonographic scan coincides with the geometric plane in which the accessory enters.

The subject devices operates in B mode using the de-aerated water immersion or balloon contact method and offers a 250° scan. The outer diameter of the insertion tube is 11.7 mm and it's working length is 1265 mm.

Both subject and predicate devices have similar design, construction, intended use, and method of operation. The only difference between the two is that the subject device's scanning plane is parallel, rather than perpendicular, to the axis of the insertion tube. The Olympus Endoscopic Ultrasound System, EU-M20, received marketing clearance in the 510(k) # K926514.

The MAJ-213 Balloon will be provided clean and should be EtO sterilized before use. The balloon is intended for single use only and should be discarded after use. All other components and related ancillary equipment of the subject device will be marketed non sterile and can be reprocessed as described in the Instruction Manuals.