

510 (k) SUMMARY

APR 15 1996

Olympus EU-M30 Endoscopic Ultrasound Center

Device Name: Olympus EU-M30 Endoscopic Ultrasound Center and ancillary equipment

Common/Usual Name: Endoscopic Ultrasound System

Classification Name: System, Imaging, Pulsed Echo, Ultrasonic Endoscope and/or Accessories

Predicate Devices: Olympus EU-M20 (K926514)
Aloka SSD-550

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Statement of Intended Use

Olympus EU-M30 Endoscopic Ultrasound center is designed to be used in combination with the Olympus GF-UM20/JF-UM20/CF-UM20 ultrasonic endoscopes, Olympus UM-2R/UM-3R ultrasonic probes, and Olympus MH-908 esophageal ultrasonic probe for observation of real-time, ultrasonic images of upper GI tract, lower GI tract, and adjacent structures.

Device Description

The EU-M30 Endoscopic Ultrasound Center allows the connection of a keyboard, monitor, video printer, video cassette recorder (VCR), Endoscopic Video Image System (EVIS), foot switch, and magnetic card reader. The front panel of the EU-M30 allows the connection of endoscope via a specially designed connector. It produces ultrasonic images using the 7.5MHz, 12.0 MHz, or 20.0 MHz transducers and provides a B-Mode display on a monitor. The EU-M30 is recommended to be used in conjunction with the Olympus GF-UM20/JF-UM-20/CF-UM20 ultrasonic endoscopes, UM-2R/UM-3R ultrasonic probe, and MH-908 esophageal ultrasonic probe. When Olympus EVIS-100 or EVIS-200 Video System is connected to the EU-M30 Center, it offers a sub-screen feature that allows the user to view both ultrasonic and video images simultaneously on a monitor. It also provides the ability to switch between ultrasonic and video images, as desired.

No components of the Olympus EU-M30 Endoscopic Ultrasound Center (Standard Set) come in contact with patient. For instructions on operation and maintenance, the user must refer to the Instruction Manual accompanied with the equipment.

The Olympus EU-M30 Endoscopic Ultrasound Center is substantially equivalent in design, material, intended use, operation, performance, and energy source to the Olympus EU-M20 Endoscopic Ultrasound Center which was cleared in 510(k) # K926514. Additionally, it is also substantially equivalent to the Aloka SSD-550 Ultrasound System marketed by Corometrics Medical System. The 510(k) # for the Aloka SSD-550 Ultrasound System is not known to Olympus America Inc.

Safety:

The Olympus EU-M30 Endoscopic Ultrasound Center is designed, manufactured and tested in compliance with the requirements of IEC-601-1, Class-I, Type BF. The ultrasound characteristics of Olympus EU-M30 Endoscopic Ultrasound Center meets the requirements of FDA's 510(k) Diagnostic Ultrasound Guidance for 1993 and 1985.

When compared to the predicate Olympus EU-M20 Endoscopic Ultrasound Center and Aloka SSD-550 Ultrasound System, the Olympus EU-M30 Endoscopic Ultrasound Center does not incorporate any significant change in intended use, method of operation, material, or design that could affect safety or effectiveness.