K 962897

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DATE PREPARED: 07-23-96 **PREPARED BY:** PAUL SILVA

510(K) SUMMARY
DEVICE: EG-3400, VIDEO GASTROSCOPE

OCT - 4 1996

1. SUBMITTER INFORMATION:

Pentax Precision Instrument Corporation
30 Ramland Road
Orangeburg, NY, 10962
TEL: (914)-365-0700

2. NAME OF DEVICE:

Trade Name: EG-3400, Video Gastroscope
Classification Name: Gastroscope, Gastro- Urology (78FDS), 876.1500

3. PREDICATED DEVICE(S) INFORMATION:

1. FG-23H, Fiber Gastroscope	Pentax	K850020
2. EC-3800L, Video Colonoscope	Pentax	K951574
3. EPM-3300, Video Processor	Pentax	K934918

4. DEVICE DESCRIPTION:

The EG-3400, Video Gastroscope, must be used with a Video Processor (a software controlled device). The endoscope has a flexible insertion tube, a control body, and umbilicus. The umbilicus provides connection to the video processor. The control body includes controls for up/ down/ left/ right angulation, air/water delivery, suction, and an accessory inlet port. The device contains light carrying bundles, to illuminate the body cavity, and a charge couple device (CCD) to collect image data. The instrument contains a working channel through which biopsy devices, or other devices, may be introduced (the instrument is supplied with two biopsy forceps). The Video Processor contains a 300 watt xenon lamp which provides white light that is filtered, via a Red, Green, Blue color wheel, and is focused at the connected video endoscope lightguide prong. The endoscope light carrying bundles present the color strobes to the body cavity and the CCD collects image data for each strobe of color. The video processor stores the CCD information until all three color strobes are completed and a full color frame is compiled. Image data and other screen display information are formatted and presented to the video outputs of the video processor for display.

5. INTENDED USE:

The EG-3400, Video Gastroscope, is intended to provide optical visualization (via a video monitor) of, and therapeutic access to, the Upper Gastrointestinal Tract. The Upper Gastrointestinal Tract includes, but is not limited to, the organs; tissues; and subsystems: Esophagus, Stomach, Duodenum, and Small Bowel. The instrument is introduced per orally when indications consistent with the requirement for procedure(s) are observed in Adult and Pediatric patient populations.

6. COMPARISON TO PREDICATED DEVICE(S):

The submission for substantial equivalence included EG-3400 literature including specifications, the identification of standard set components, and identification of optional accessories, comparision tables were provides to illustrate the comparisons to the predicated devices. The submission for substantial equivalence was not based on an assessment of clinical performance data.