

DEVICE: ES-3800, VIDEO SIGMOIDOSCOPE

PREPARED BY: PAUL SILVA DATE SUMMARY PREPARED: 02/04/95

1. SUBMITTER INFORMATION:

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

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2. NAME OF DEVICE:

Trade Name: ES-3800, Video Sigmoidoscope
Classification Name: Sigmoidoscope, flexible (78FAM), 876.1500

3. PREDICATED DEVICE(S) INFORMATION:

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|--------------------------------------|--------|---------|
| 1. FS-34, Fiber Sigmoidoscope | Pentax | K792341 |
| 2. VB-1530/ 1830, Video Bronchoscope | Pentax | K934920 |
| 3. EPM-3300, Video Processor | Pentax | K934918 |

4. DEVICE DESCRIPTION:

The ES-3800, Video Sigmoidoscope, 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, CO2 delivery, 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 ES-3800, Video Sigmoidoscope, is intended to provide optical visualization of, and therapeutic access to, the Lower Gastrointestinal Tract (extent of exam, sigmoid colon). The Lower Gastrointestinal Tract includes, but is not restricted to, the organs; tissues; and subsystems: Large Bowel. The instrument is introduced per rectally when indications consistent with the requirement for the procedure are observed in Adult and Pediatric patient populations.

6. COMPARISON TO PREDICATED DEVICE(S):

The submission for substantial equivalence included ES-3800 literature including specifications, the identification of standard set components, and identification of optional accessories, comparison 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.