

510(k) Summary of Safety and Effectiveness

K 963323

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1.0 **Classification Name:**

Endoscope and/or accessories

2.0 **Common/Usual Name:**

Video Image Processor/Video Enhancer

3.0 **Trade Name:**

ENDO VIP

4.0 **Equivalence:**

The device is equivalent to devices sold by Karl Storz.

5.0 **Description:**

The Video Image Processor ENDO VIP 5588 enhances the detail definition of medical video images. It is connected between video camera and video monitor. The enhancement level is manual controlled in 3 steps.

6.0 **Intended Use:**

Video Image Processor ENDO VIP 5588 is a video contrast enhancer and is used in connection with a video system. It enhances the detail definition of medical video images. It is used as an accessory during diagnostic and therapeutic interventions in video endoscopy and video microscopy.

7.0 **Technological Characteristics:**

The Video Image Processor ENDO VIP 5588 has a digital video processor and uses a fixed algorithm with user-variable parameters to improve detail visibility in video images. Y/C video signals, which are compatible with NTSC and PAL video standards, are processed in real time.

8.0 **Performance Data:**

Independent laboratories tested the Video Image Processor ENDO VIP 5588 according to specified standards IEC601-1, IEC601-1-2 and UL2601-1.

9.0 **Clinical Tests:**

No clinical tests performed.

10.0 **Data Conclusion:**

Video Image Processor ENDO VIP 5588 is designed and tested to guarantee the safety and effectiveness, if the device is used according to the instruction manual.

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Date:

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