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510(k) Summary
Galileo Electro-Optics Corporation
Galileo Hysteroscopes and Laparoscopes

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1. Sponsor/Applicant Name and Address

Galileo Electro-Optics Corporation
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Contact Person

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Date of Summary Preparation

June 11, 1996

2. Device Name

Proprietary Name:	Galileo Hysteroscopes and Laparoscopes
Common/Usual Name:	Hysteroscopes and Laparoscopes
Classification Name:	Hysteroscopes and accessories
	Laparoscopes and accessories

3. Identification of Predicate or Legally Marketed Device(s)

The Galileo Hysteroscopes and Laparoscopes are substantially equivalent to several legally marketed endoscopes including the Karl Storz Hysteroscopes and Laparoscopes, (K88270 and K935277) and the Richard Wolf Hysteroscopes and Laparoscopes (K880314 and K770378).

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4. Device Description

The Galileo Hysteroscopes and Laparoscopes are a line of reusable rigid endoscopes based on existing endoscope technology. The Galileo Hysteroscopes and Laparoscopes will be available in various lengths, diameters and configurations for the convenience of the user. Two designs of endoscopes are available:

Galileo Rod and Lens Design Endoscope:

The rod and lens design Galileo Endoscope functions by light being transmitted from a standard external high intensity light source through optical fibers to the distal tip of the endoscope. The image of the target is then transmitted from the distal end via an objective lens and an alternating set of rod and lenses to a proximal eyepiece. The image can be viewed directly or it may be transmitted through a video camera to a video monitor.

Galileo Fiber Optic Design Endoscope:

The fiber optic design Galileo Endoscope functions by light being transmitted from a standard external high intensity light source through optical fibers to the distal tip of the endoscope. The image of the target is then transmitted from the distal end via an objective lens and a fiberoptic imaging bundle (instead of a rod and lens) to a proximal eyepiece. The image can be viewed directly or it may be transmitted through a video camera to a video monitor.

5. Intended Use

The Galileo Hysteroscopes are rigid endoscopes intended for direct visualization of cervical canal and uterine cavity for diagnostic and surgical procedures during gynecological procedures. The Galileo Laparoscopes are intended for direct visualization of the organs within the peritoneum for diagnostic and surgical procedures on the female genital organs. The Galileo Laparoscopes are designed to be introduced through natural body cavities or through introducers, needles, trocars, catheters, sheaths or other devices with thru-lumens having inside diameters larger than the outside diameter of the endoscope.

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6. Comparison of Technological Characteristics

The Galileo Hysteroscopes and Laparoscopes and the substantially equivalent devices are identical in intended use in that they are all rigid endoscopes intended to be passed through a lumen of an introducer or into natural body cavities for visualization of body cavities, tissues, organs or canals.

The Galileo Hysteroscopes and Laparoscopes and the substantially equivalent devices are similar in designs in that they all offer various configurations including rod/lens or fiberoptic design, optional working channels, several OD's and lengths, and use external light sources, and similar stainless steel materials.

The Galileo Hysteroscopes and Laparoscopes and the substantially equivalent devices are similar in technological characteristics in that they offer a channel for either viewing body cavities, tissues, organs or canals and an optional channel for passing instruments into the desired anatomical sites.