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510(k) Summary
Galileo Electro-Optics Corporation
Galileo Endoscopes

1. SPONSOR/APPLICANT NAME AND ADDRESS

Galileo Electro-Optics Corporation
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Contact Person

Kin M. Wong, Director of Quality Assurance

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October 30, 1996

2. DEVICE NAME

Proprietary Name: Galileo Endoscopes
Common/Usual Name: Endoscope
Classification Name: Endoscope and accessories

3. IDENTIFICATION OF PREDICATE OR LEGALLY MARKETED DEVICE(S)

The Galileo Endoscopes are substantially equivalent to several legally marketed endoscopes including the Imagyn Laparoscope manufactured by Imagyn Medical, the Optimed Rigid Fiber Optic Endoscope manufactured by Optimed Technologies, Inc., the Fiber Optic Laparoscope manufactured by Medical Dynamics and the Model 2010 Rigid Fiber Optic Sinuscope, the Model 4200 Fiber Optic Laparoscope and Fiber Optic Cholescope, and the Rigid Sinuscope all manufactured by Saratoga Medical, and the Hopkins Laparoscopes and Thoracoscope manufactured by Karl Storz Endoscopy.

4. DEVICE DESCRIPTION

The Galileo Endoscopes are a line of reusable rigid endoscopes based on existing endoscope technology. The Galileo Endoscopes 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 Endoscopes are rigid endoscopes intended for direct visualization of body cavities, hollow organs, and canals. The Galileo Endoscopes 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. The Galileo Endoscopes indications for use include thoracoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and general laparoscopy.

6. STATEMENT OF HOW THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARE TO THOSE OF THE PREDICATE OR LEGALLY MARKETED DEVICE(S) CITED

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

The Galileo Endoscopes and the substantially equivalent devices are similar in technological characteristics in that they offer a channel for viewing body cavities, tissues, organs or canals.