

K981828

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**510(k) Summary
Galileo Corporation
Galileo Disposable Hysteroscopes**

1. SPONSOR/APPLICANT NAME AND ADDRESS

Galileo Corporation
Galileo Park
P.O. Box 550
Sturbridge, MA 01566
Telephone: (508) 347-9191

Contact Person

Debby Iampetro
Director of Quality Assurance and Regulatory Affairs

Date of Summary Preparation

May 20, 1998

2. DEVICE NAME

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

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

The Galileo Hysteroscopes are substantially equivalent to several legally marketed endoscopes including the Galileo Disposable Diagnostic Hysteroscopes (K974297), Galileo Reusable Hysteroscopes (K962116), U.S. Surgical Surgiview Endoscopes, (K925968) and the Richard Wolf Hysteroscopes and Laparoscopes (K880314 and K770378).

4. DEVICE DESCRIPTION

The Galileo Disposable Hysteroscopes are a line of disposable endoscopes based on existing endoscope technology. The Galileo Disposable Hysteroscopes will be available in several sizes and lengths.

The Galileo Disposable Hysteroscopes are fiber optic design endoscopes that are offered in disposable configurations only. Fiberoptic design endoscopes function 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 to a proximal eyepiece. The image can be viewed directly or it may be transmitted through a video camera to a video monitor.

The Disposable Hysteroscopes are offered with a coupler that includes a light source which is provided by Galileo Electro-Optics Corporation. The Galileo coupler is compatible only with the Galileo Disposable Hysteroscopes and the other cleared commercially available Galileo endoscopes.

5. INTENDED USE

The Galileo Disposable Hysteroscopes are endoscopes intended for direct visualization of cervical canal and uterine cavity for diagnostic and surgical procedures during gynecological procedures. The Galileo Disposable Hysteroscopes are designed to be introduced through natural body cavities or through introducers, catheters, sheaths or other devices with thru-lumens having inside diameters larger than the outside diameter of the endoscope. The surgical indications include directed biopsy, removal of submucous fibroids and large polyps, submucous myomectomy, transection of intrauterine adhesions and septa and endometrial ablation.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Galileo Disposable Hysteroscopes and the substantially equivalent devices are identical in intended use in that they are all 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 Disposable Hysteroscopes 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 Disposable Hysteroscopes 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.

Testing was performed to:

- determine the capability of the units to transmit image after deflection of the sheath portion of the device through a specific set of distances, and
- demonstrate that the polyimide sheath is equivalent to the stainless steel sheath in the framework of the rigid scope.

Samples of each type of hysteroscope containing the lens, image fiber, and illumination fiber were used for this testing. A baseline optical test was performed prior to the deflection test. The deflection test was performed by holding the shaft of one sample in one of the jaws of an Instron Tensile Tester and applying weight at the other end of the shaft until a desired deflection was obtained or until the tube is damaged at the plane it is held at in the fixture. All samples were tested ensuring the distance from the point of hold to the point of application of weight is constant. The hysteroscope assemblies were then retested for the desired image conduction properties.

The acceptance criteria for this testing were all optical tests performed before and after the deflection test of the sample must pass the optical acceptance criteria.

The field of view, angle of view, resolution on axis and uniformity of illumination were evaluated for acceptance criteria. The results of this testing showed that both the stainless steel and the polyimide sheathed sample scopes showed no change in any tested optical performance criteria. These results demonstrate that both samples maintained structural integrity of the optics assembly when subjected to the test protocol.

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Testing was also performed to determine thermal safety of the Galileo Disposable Hysteroscopes according to IEC 601-2-18. The Disposable Hysteroscopes passed the Thermal Safety Testing. Electrical safety testing will also be performed on the Disposable Hysteroscopes prior to commercial distribution.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Galileo Corporation
c/o Ms. Mary McNamara-Cullinane, RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760Re: K981828
Galileo Corporation Disposable Hysteroscopes
Dated: May 20, 1998
Received: May 22, 1998
Regulatory Class: II
21 CFR 884.1690/Procode: 85 HIH

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981828

Device Name: Galileo Disposable Hysteroscopes

Indications For Use:

The Galileo Disposable Hysteroscopes are endoscopes intended for visualization of the cervical canal and uterine cavity for diagnostic and surgical procedures during gynecological procedures. The Hysteroscope diagnostic indications include abnormal uterine bleeding, infertility and pregnancy wastage, evaluation of abnormal hysterosalpingogram, intrauterine foreign body, amenorrhea and pelvic pain. The Hysteroscope is indicated for surgical procedures such as directed biopsy, removal of submucous fibroids and large polyps, submucous myomectomy, transection of intrauterine adhesions and septa and endometrial ablation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Sattling
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981828

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)