

AUG 6 1998

510(k) Summary
Galileo Corporation
Galileo Disposable Endoscopes

K981928

1. SPONSOR/APPLICANT NAME AND ADDRESS

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

CONTACT PERSON

Debbie Iampietro
Director of Quality Assurance

DATE OF SUMMARY PREPARATION

June 1, 1998

2. DEVICE NAME

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

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

The Galileo Disposable 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 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 Disposable Endoscopes are a line of endoscopes based on existing endoscope technology. The Galileo Disposable Endoscopes will be available in various lengths, diameters and configurations for the convenience of the user.

5. INTENDED USE

The Galileo Disposable Endoscopes are endoscopes intended for direct visualization of body cavities, hollow organs, and canals. The Galileo Disposable Endoscopes are designed to be introduced through natural body cavities or surgical incisions 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 Disposable Endoscopes indications for use include choledoscopy, cystoscopy, ureteroscopy, thoracoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, general laparoscopy and urological applications.

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

The Galileo Disposable Endoscopes 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 Endoscopes 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 Endoscopes 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 6 1998

Galileo Electro-Optics Corporation
c/o Medical Device Consultants, Inc.
Mary McNamara-Cullinane
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K981928
Trade Name: Galileo Disposable Endoscopes
Regulatory Class: II
Product Code: GCJ
Dated: June 1, 1998
Received: June 2, 1998

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.

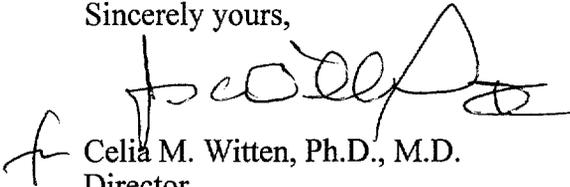
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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) 594-4595. 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/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981928

Device Name: Galileo Disposable Endoscopes

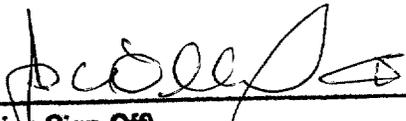
Indications For Use:

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The indications include choledoscopy, cystoscopy, ureteroscopy, bronchoscopy, thoracoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, general laparoscopy and urological applications.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981928

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)