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K971896

APPENDIX E

510(k) Summary
Galileo Corporation
Galileo Micro Coupler

1. Sponsor/Applicant Name and Address

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

Contact Person

Kin M. Wong, Director of Quality Assurance

Date of Summary Preparation

October 6, 1997

2. Device Name

Proprietary Name:	Galileo Micro Coupler
Common/Usual Name:	Endocoupler
Classification Name:	Coupler

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

The Galileo Micro Coupler is substantially equivalent to Precision Optics Corp. Coupler (K903458).

4. Device Description

The Galileo Micro Couplers are a line of reusable optical couplers used in the transfer of image from an endoscope to a video camera for either image recording or viewing on a monitor. The Galileo Micro Couplers are available in several configurations which will allow coupling to different Endoscopes and camera.

5. Intended Use

The Galileo Micro Couplers act as an interface to transmit the optical image from the endoscope to the camera for either direct viewing on a monitor or video image recording.

6. Comparison of Technological Characteristics

The Galileo Micro Couplers and the substantially equivalent devices are identical in intended use in that they are all use lenses, prisms (including split beams) and windows to transmit the image from the endoscope to the camera.

The Galileo Micro Couplers and the substantially equivalent devices are identical in the various mechanical interfaces with the endoscope and the camera.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 1997

Mr. Kin Wong
Director, Quality Assurance
Galileo Electro-Optics Corporation
Galileo Park
P.O. Box 550
Sturbridge, Massachusetts 01566

Re: K971896
Galileo Micro Coupler
Dated: August 26, 1997
Received: September 2, 1997
Regulatory class: II
21 CFR §884.1720/Product code: 85 HET
21 CFR §884.1690/Product code: 85 HIH

Dear Mr. Wong:

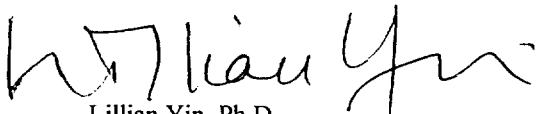
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4613. 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/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): K971896

Device Name: Galileo Micro Coupler

Indications For Use:

The Galileo Micro Coupler is indicated for use with endoscopy. It is an interface which allows the transmission of optical image from the endoscope to a video camera for video recording or viewing on a monitor.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971896