K970875

AMERICAN MEDICAL DEVICES, Inc.

1100 Northside Drive Atlanta, Georgia 30318

MAY 20 1997

February 27, 1997

Premarket Notification [510(k)] Summary

Submitter: American Medical Devices, Inc
1100 Northside Drive
Atlanta, GA 30318
Phone: (404) 815-5233
Fax: (404) 815-5235

Official Correspondent: Frank J. Tighe

Trade Name: The American Medical Devices, Inc., 19 and 20 Ga. Endolight™ Fiberoptic Endo-Illuminator.

Common Name: Fiberoptic Endo-Illuminator

Registration Number: We have registered but have not received our application back as of this date.

Class: Class II

Class Name: We were unable to find the device listed in the classification regulations, 21 CFR Parts 862-892 [807.87 (c)].

Panel: Ophthalmic

Product Code: HQE

Toll-Free	Direct	Facsimile	Internet
800-793-1473	404-815-5233	404-815-5235	ftighe@americanmedicaldevices.com

Device Description: The American Medical Devices, Inc., 19 and 20 ga. Endolight™ Fiberoptic Endo- Illuminators are for illumination during ophthalmic surgery. The device consists of a stainless steel needle with a delrin handpiece, PMMA fiberoptic fiber with plastic cladding and an aluminum connector. This device connects to any conventional light source via an aluminum accessory adapter, which is packaged separately.

Statement of indications for use. - For illumination during ophthalmic surgery.

Substantial Equivalence Comparison

Substantial Equivalence Comparison

	American Medical Devices, Inc.	Storz	Grieshaber & Co.
Packaging Tyvek to Poly	X	X	X
For illumination During ophthalmic surgery	X	X	X
Materials: Stainless Steel Needle, PMMA Fiberoptic Fiber, Delrin Handpiece ,	X	X	X
Aluminum Connector	X		X
Sterilization ETO	X	X	X

Sterility

The Device will be ETO Sterilized.

The method used to validate the sterilization cycle is AAMI Overkill Method

Packaging Material: Tyvek Pouch with a Ploymylar Sheath.

The SAL is 10 to the –6.

The maximum levels of residues of **ethylene oxide**: 25 parts per million; **ethylene chlorohydrin:** 25 parts per million and **ethylene glycol:** 250 parts per million.

This device is non-pyrogenic and the LAL Method is used to make that determination.

Pyrogens: We control the manufacturing environment to lessen the likelihood of pyrogen causing bacteria. In addition the LAL Method is used to determine that each lot is non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1997

Mr. Frank J. Tighe
American Medical Devices, Inc.
1100 Northside Drive
Atlanta, GA 30318

Re: K970875
Trade Name: Endolight™ Fiberoptic
Endo-Illuminator 19 and 20 ga.
Regulatory Class: II
Product Code: MPA
Dated: February 27, 1997
Received: March 10, 1997

Dear Mr. Tighe:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 at (301) 443-6597.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AMERICAN MEDICAL DEVICES, Inc.

1100 Northside Drive Atlanta, Georgia 30318

(510(k) Number (if known): K970875

Device Name: The American Medical Devices, Inc 19 and 20 ga. Endolight™ Fiberoptic Endo-Illuminator

Indications For Use:

For illumination during ophthalmic surgery

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K970875

Prescription Use ___X___ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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