K970878

MAY - 6 1997

1100 Northside Drive Atlanta, Georgia 30318

February 27, 1997

Premarket Notification [510(k)] Summary

Submitter: American Medical Devices, Inc
1100 Northside Drive
Atlanta, GA 30318
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Official Correspondent: Frank J. Tighe

Trade Name: The American Medical Devices, Inc., 19 and 20 Ga. Endolight™ Regular and Fine Monofilaments.

Common Name: Fiberoptic Bare End Fiber.

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: MPA

Device Description: The American Medical Devices Endolight™ Regular and Fine Monofilaments are for illumination during surgery. The Regular Monofilament inserts into any standard pic set. The Fine Monofilament inserts into any standard fiberoptic forceps. These fibers allow the surgeon to use bi-manual technique during surgical procedures. The devices are identical except for the fact that the Regular Monofilament is a 19 ga. fiber and the Fine Monofilament is a 20 ga. fiber. Please see Device Replica Diagram in Appendix C.

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

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Statement of indications for use. - For illumination during surgery. Regular Monofilament – Inserts into any standard Fiberoptic Pic Set.
Fine Monofilament – Inserts into any standard Fiberoptic Forceps.

Substantial Equivalence Comparison

	American Medical Devices, Inc.	Gamp & Assoc.	Grieshaber
PMMA Fiber	X	X	X
PMMA Cladding	X	X	X
Aluminum Connector	X	X	X
For Illumination During Surgery	X	X	X
ETO Sterilized	X	X	X

The American Medical Devices, Inc Regular and Fine Monofilaments are produced and sterilize same locations as the Grieshaber products.

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.