AUG - 6 1997

K971853

AMDI AMERICAN MEDICAL DEVICES, Inc.

1100 Northside Drive Atlanta, Georgia 30318

May 16, 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: Endoview™ Sapphire Lens Set

Common Name: Surgical Contact Lens Set

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

Class: Class II

Class Name: Unknown

Panel: Ophthalmic

Product Code: 86HDQ

Device Description
The Endoview™ Sapphire Contact Lens Set consists of one sterilization container, one lens ring (either infusion or non-infusion), and one each of the following lenses: Plano Concave, Symmetric Concave-Concave, Asymmetric Concave-Concave, Prism 15° - Concave, Prism 30° Concave, and a Prism Concave-Concave Lens. The lenses, rings and sterilization container may be sold separately or as a set.
During vitreoretinal surgery, the surgeon requires the aid of a contact lens in order to visualize the posterior segment of the eye. First, the ring is sewn onto the sclera to hold the lens in place on the cornea.

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

The customer has the option of choosing a ring with an infusion port, which eliminates the need for the surgeon to constantly place irrigant on the corneal. This type of ring device is currently available from Ocular Instruments (510(k) 902496. Once the ring is in place, the surgeon places one of the lenses in the ring in order to visualize the posterior segment of the eye. The surgeon changes the lenses during the case depending on where visualization is required. Most lenses on the market have been manufactured from quartz and high refractive index plastic because of their low cost and good refractive properties. However, these materials can be easily scratched, chipped and damaged during normal cleaning, handling and sterilization. Single Crystal Sapphire, on the other hand, is an ideal material for ophthalmic surgery because of its wide transmission band, extreme hardness and excellent chemical resistance.

Statement of indications for use. For magnification during vitreoretinal surgery.

Substantial Equivalence Comparison

	American Medical Devices, Inc.	DORC	Grieshaber	Ocular Instruments
Flat Lens for Central viewing	X	X	X	X
15 degree lens for mid-Peripheral viewing	X	X	X	X
30 degree lens for wide field viewing	X	X	X	X
Bi-concave lens For air filled phakik Patients	X	X	X	X
Shipped Non Sterile	X	X	X	X
Sterilize with either ETO Or steam	X	X	X	X
Sterilization Container	X	X	X	X
Infusion Lens Ring	X			X
Lens Ring**	X	X	X	X

** All lens sets have lens rings. American Medical Devices, Inc and Ocular Instruments offer a lens ring with an infusion port.

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Sterility

The Device is shipped non-sterile to the user. The user may either ETO or steam sterilize the lenses according AAMI or USP Standards. ETO and Steam Sterilization of Sapphire in Ophthalmic Devices has been performed since the mid 1980's A user instruction sheet is included with each lens set (See Page 4 of this summary), which instructs the user to clean the lenses immediately after used with warm soapy water. In addition, the instructions clearly state to only sterilize thoroughly cleaned instruments and to Steam or ETO sterilize the lenses prior to use according to AAMI or USP standards.

Packaging

The device is shipped in a high temperature plastic sterilization container, which contains a custom-molded cavity to secure the lenses and ring during sterilization.

Materials Used in Manufacture

Lenses – The lenses are manufactured from sapphire. Sapphire has been approved for use in ophthalmic devices since the mid-1980s with product code 86HNN and with the following 510(k)s: K853129 Rudolph Beaver Inc, Beaver Multipurpose Sapphire Knife. K860852 Med-Tech Development Corp, Sapphire Blade Surgical Knife. K861744 Keeler Instruments, Inc., Sapphire Knife Blade. These lenses are non-invasive and only contact the cornea during the surgical procedure whereas the sapphire knives are invasive and are used to make an entry into the cornea and actually enter the anterior chamber of the eye.

Sterilzation Container: Manufactured from high temperature plastic. The Ocular Instruments and DORC sterilization containers are also manufactured from high temperature plastic.

Lens Ring: Aluminum. Ocular Instruments, Grieshaber, and DORC all use aluminum for their lens rings

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ENDOVIEW™ SAPPHIRE CONTACT LENS SET

USER, CLEANING AND STERILIZATION INSTRUCTIONS

THIS DEVICE IS NON STERILE

Device Description

The Endoview™ Sapphire Contact Lens Set consists of one sterilization container, one lens ring (either infusion or non-infusion), and one each of the following lenses: Plano Concave, Symmetric Concave-Concave, Asymmetric Concave-Concave, Prism 15° - Concave, Prism 30° Concave, and a Prism Concave-Concave Lens. The lenses, rings and sterilization container may be sold separately or as a set.

During vitreoretinal surgery, the surgeon requires the aid of a contact lens in order to visualize the posterior segment of the eye. First, the ring is sewn onto the sclera to hold the lens in place on the cornea. The customer has the option of choosing a ring with an infusion port, which eliminates the need for the surgeon to constantly place irrigant on the corneal. Once the ring is in place, the surgeon places one of the lenses in the ring in order to visualize the posterior segment of the eye. The surgeon changes the lenses during the case depending on where visualization is required. Most lenses on the market have been manufactured from quartz and high refractive index plastic because of their low cost and good refractive properties. However, these materials can be easily scratched, chipped and damaged during normal cleaning, handling and sterilization. Single Crystal Sapphire, on the other hand, is an ideal material for ophthalmic surgery because of its wide transmission band, extreme hardness and excellent chemical resistance.

Statement of indications for use. For magnification during vitreoretinal surgery.

CLEANING

Clean the lenses immediately after use with warm soapy water.

STERILIZATION THIS DEVICE IS NON STERILE.

Only sterilize the product after it has been thoroughly cleaned. ETO or steam sterilize the product prior to use according AAMI or USP Standards.

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ENDOVIEW™ SAPPHIRE LENS SET CONTENTS

Trade or proprietary or model name	Model Number
1. Endoview™ Sapphire Lens Set (Consisting of 1 each of the following)**	1. 600.00
2. Endoview™ Flat Sapphire Lens (Machemer)	2. 600.01
3. Endoview™15° Prism Sapphire Lens (Tolentino)	3. 600.02
4. Endoview™ 30° Prism Sapphire Lens (Tolentino)	4. 600.03
5. Endoview™ Biconcave Sapphire Lens (Landers)	5. 600.04
6. Endoview™ Asymmetric Biconcave Sapphire Lens (de Juan)	6. 600.05
7. Endoview™ 30° Biconcave Sapphire Lens (Woldoff,Tano)	7. 600.06
8. Endoview™ Sapphire Lens Set Sterilization Container	8. 600.07
9. Endoview™ Infusion Lens Ring**	9. 600.08
10. Endoview™ Lens Ring**	10. 600.09

**The customer has the option of choosing the lens ring with or without infusion.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 1997

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

Re: K971853
Trade Name: Endoview™ Sapphire Lens Set
Regulatory Class: II
Product Code: 86 HJK
Dated: May 16, 1997
Received: May 20, 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 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/dsmamain.html".

Sincerely yours,

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

Enclosure

AMDI AMERICAN MEDICAL DEVICES, Inc.

1100 Northside Drive Atlanta, Georgia 30318

(510(k) Number (if known):

Device Name: Endoview™ Sapphire Lens Set

Indications for Use:

For magnification during vitreoretinal surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W. C. Brown, Ph.D.

(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K971853

Prescription Use___X___
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)

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