9/16/99

K982599

Premarket Notification [510(k)] Summary

Submitter: Ophthalmic Solutions, LLC
2179 Northlake Parkway
Building 5, Suite 115
Tucker, Georgia 30084
Telephone: (770) 939-9040
Fax: (770) 934-4084

Official Correspondent: Daria Ann Fremstad

Trade Name: Ophthalmic Solutions, LLC, The Fremstad Ring™

Common Name: Sponge, Ophthalmic

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

Class: Class II

Class Name: 886.4790

Panel: Ophthalmic

Product Code: HOZ

Device Description: The Ophthalmic Solutions, LLC, The Fremstad Ring™ is used as a sponge. The device material consists of cellulosic and synthetic fibers. 14mm diameter, round, inner diameter 11mm, thickness 0.1 mm.

Statement of indications for use. - For use as an ophthalmic sponge, used to absorb fluids from the surgical area during ophthalmic procedures, not intended to contact the cornea.

Substantial Equivalence Comparison

	Ophthalmic Solutions, LLC	Visi-Spear Eye Sponge by Visitec	Cellulose Surgical Spear Distributed by Akorn
Sterile	X	X	X
Material Cellulosic and Synthetic Fibers	X		
Material Cellulose		X	X
Sterilization ETO	X		
Sponge	X	X	X

Sterility

The Device will be ETO Sterilized.

The method used to validate the sterilization cycle is ANSI/AAMI Overkill, ISO 11135-1994.

Packaging material: Tyvek Pouch with a Polymylar Sheath.

The SAL is 10 to the -6.

Biocompatibility:

Test Facility:

North American Science Associates, Inc.
2261 Tracy Road
Northwood, OH 43619-1397

Study Title:

1. Cytotoxicity Study- Using The ISO Elution Method:

Test Article: Fremstad Ring™
Identification No: Lot 1000

Conclusion: Under the conditions of this study, the MEM test extracts showed no evidence of causing cell lysis or toxicity. The MEM test extracts were not cytotoxic and met the requirements of the test. The negative controls, reagent controls, and the positive controls performed as anticipated.

Study Title:

2. ISO Ocular Irritation Study In The Rabbit: (Single Exposure)

Test Article: Fremstad Ring™
Identification No: Lot 1000

Conclusion: Under the conditions of this study, the SC and CSO test article extracts would not be considered irritants to the ocular tissue of the rabbit.

Study Title:

3. ISO Sensitization Study in the Guinea Pig (Maximization Method)

Test Article: Fremstad Ring™
Identification No: Lot 1000

Conclusion: Under the conditions of this study, the SC and CSO test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 1999

Ms. Daria Ann Fremstad
Official Correspondent
Ophthalmic Solutions, LLC
2179 Northlake Parkway
Building 5, Suite 115
Tucker, GA 30084

Re: K982599
Trade Name: The Fremstad Ring™
Regulatory Class: II
Product Code: HOZ
Dated: January 27, 1999
Received: January 29, 1999

Dear Ms. Fremstad:

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 legally marketed predicate 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

510(k) Number (if known): K982599

Device Name: The Fremstad Ring™

Indications For Use: Ophthalmic sponge, used to absorb fluids from the surgical area during ophthalmic procedures, not intended to contact the cornea.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin F Warburton

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K982599

Prescription Use X OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)