K973293
page 1

NOV 18 1997

Section 9 - Summary of Safety and Effectiveness

Date of Preparation: 8/10/1997

Device Name: Syntec, Inc. True Light End Irrigating Endoilluminator.

Classification Name: Opthamalic Endoilluminator, 86MPA

Manufacturer: Syntec, Inc. is located at 733 Mansion Road, Winfield, MO 63389. Telephone (314) 566-6500 and Fax number is (314) 566-6535

510(k) Submitter: Syntec, Inc. is located at 812 Truman Blvd. Crystal City, MO 63389. Telephone (314) 931-2204 and Fax number is (314) 931-6029.

Contact Person: Nathan H. Lewis

Predicate Device: This device is substantially equivalent to the Grieshaber Disposable End Irrigating Light Pipe catalog numbers 630.02G and 631.02 20G manufactured by Grieshaber & Co. Inc. located at 1945 Vaughn Road, Kennesaw, GA 30144. This device was the subject of Premarket Notification K884043.

Device Description: The End Irrigating Endoilluminator comprises of five basic components. The handpiece handle. The handpiece tube. The fiberoptic cable. The fiber optic cable sheath and the connector.

Intended Use: The Syntec, Inc. True Light End Irrigating Endoilluminator is used to illuminate with visible spectrum light the intraocular portion of the eye for improved visualization and to irrigate tissue, during vitreo-retinal surgery.

Clinical and Non-Clinical Similarities and Differences:

The Syntec Inc. True Light End Irrigating Endoilluminator six basic components: the handpiece tube, the fiberoptic cable, the fiber optic cable sheath, the light source connector, and the irrigant connection.

The Syntec Inc. True Light End Irrigating Endoilluminator is used to illuminate with visible spectrum light the intraocular portion of the eye for improved visualization and to provide irrigation during vitreo-retinal surgery.

The Syntec, Inc. True Light End Irrigating Endoilluminator and the Grieshaber Disposable End Irrigating Light Pipe are

K973293
page 2

both substantially equivalent in that they are used for the same clinical purpose, ie: to illuminate with visible spectrum light the intraocular portion of the eye for improved visualization and to provide irrigation during vitreo-retinal surgery.

The devices are of a similar design and are made using the same materials except for the zinc connector used with the Syntec design. The handpiece tube is made of surgical grade stainless steel. The fiberoptic cable is made with a polystyrene core and a polymethylmethacrylate cladding. The fiber optic cable sheath is made of PVC tubing.

The device is biocompatible with the body tissue and fluids that it contacts as it is made of the same materials as the predicate device. These materials meet US Pharmacopoeia Class VI criteria and are widely used in many other medical products. The device is sterilized using ethylene oxide gas which is then validated by the overkill method.

The light output intensity and spot size is the same as the predicate device. The only device differences are cosmetic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Vaughan Weeks
7346 West River Rd.
Caledonia, WI 53108

NOV 18 1997

Re: K973293
Trade Name: Syntec, Inc., True Light End Irrigating Endoilluminator
Regulatory Class: II
Product Code: 86 MPA
Dated: September 2, 1997
Received: September 2, 1997

Dear Mr. Weeks:

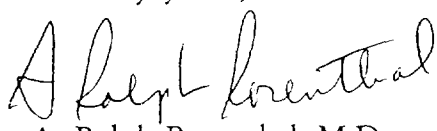
We have reviewed your Section 510(k) notification of intent to market the device referenced Gbove and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Section 8 - Indications for Use Statement

510(k) Number(if known): K973293

Device Name: Syntec, Inc., True Light End Irrigating Endoilluminator

Indications for Use: The Syntec, Inc. True Light End Irrigating Endoilluminator is used to illuminate with visible spectrum light the intra ocular portion of the eye for improved visualization and to provide irrigation during vitreo-retinal surgery.

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

Jan C Gillaway

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K973293

Prescription Use ✓
(Per 21 CFR 801.109)