

NOV 14 1997

Section 9 - Summary of Safety and Effectiveness

Date of Preparation: August 3, 1997

Device Name: Syntec, Inc. True Light Endoilluminator with Pick

Classification Name: Ophthalmic 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 733 Mansion Road, Winfield, MO 63389. Telephone (314) 566-6500 and Fax number is (314) 566-6535.

Contact Person: Nathan H. Lewis

Predicate Devices: Grieshaber Disposable Standard Micro Lite Pipe with Pic, catalog numbers 630.06 20G and 631.06 20G manufactured by Grieshaber & Co. Inc. located at 1945 Vaughn Road, Kennesaw, GA 30144. This device was the subject of Premarket Notification K875004.

Gamp & Associates Disposable Fiberoptic Endoilluminator with Pick. 16818 Kingstowne Way Drive, Ballwin, MO 63011.

Device Description: The Endoilluminator with Pick is comprised 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. Disposable Endoilluminator with Pick is used to illuminate with visible spectrum light the intraocular portion of the eye for improved visualization and to manipulate tissue, during vitreo-retinal surgery.

Clinical and Non-Clinical Similarities and Differences:

The Endoilluminator with Pick is comprised of five basic components: the handpiece tube, the fiberoptic cable, the fiber optic cable sheath and the connector.

The Syntec, Inc. Endoilluminator with Pick is used to illuminate with visible spectrum light the intraocular portion of the eye for improved visualization during vitreo-retinal surgery.

The Syntec, Inc. True Light Endoilluminator with Pick, the Grieshaber Endoilluminator with Pick, and the Gamp & Associates Endoilluminator with Pick are all 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 manipulate tissue 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 with which it comes in contact 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.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 4 1997

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

Re: K973290

Trade Name: Syntec, Inc., True Light Endoilluminator with Pick  
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 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 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.

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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): K973290

Device Name: Syntec, Inc., True Light Endoilluminator with Pick

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

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

*J. C. Callaway*  
(Division Sign-Off)  
Division of Ophthalmic Devices  
510(k) Number K973290

Prescription Use ✓  
(Per 21 CFR 801.109)