

K971338

MAY -6 1997

Section 9 - Summary of Safety and Effectiveness

Date of Preparation: March 15, 1997

Device Name: Syntec, Inc. Disposable Bare End Fiber

Classification Name: Ophthalmic Endoilluminator, 86MPA

Manufacturer: Syntec, Inc. is located at 812 Truman Blvd., Crystal City, MO 63019. The phone number is (314) 931-2204 and the fax number is (314) 931-6029.

510(k) Submitter: Syntec, Inc. is located at 812 Truman Blvd., Crystal City, MO 63019. The phone number is (314) 931-2204 and the fax number is (314) 931-6029. Contact person: Nathan H. Lewis.

Predicate Device: Grieshaber Disposable Monofilament catalog number 630.78 manufactured by Grieshaber & Co., Inc. located at 1945 Vaughn Road, Kennesaw, GA 30144.

Device Description: The Bare End Fiber is comprised of five basic components: the handpiece tube, the fiberoptic cable, the fiber optic cable sheath and the connector.

Intended Use: The Syntec, Inc. Disposable Bare End Fiber is used to illuminate with visible spectrum light the intraocular portion of the eye for improved visualization during vitreo-retinal surgery.

Clinical and Non-Clinical Similarities and Differences: The Syntec, Inc. Disposable Bare End Fiber and the Grieshaber & Co. Disposable Monofilament are substantially equivalent since they both are used for the same clinical purpose, ie: to illuminate with visible spectrum light the intraocular portion of the eye for improved visualization during vitreo-retinal surgery.

Both devices are of a similar design and are made using the exact same materials. 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 and the connector is made of 6063 aluminum.

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The device is biocompatible with the body tissue and fluids that it comes in contact with 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.