

K904555

Section 9 - Summary of Safety and Effectiveness

MAR 31 1997

Date of Preparation: March 11, 1997

Device Name: Syntec, Inc. Tru Light Endo Illuminator

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 Standard Micro Lite Pipe catalog numbers 630.77 20G and 631.77 20G manufactured by Grieshaber & Co. Inc. located at 1945 Vaughn Road, Kennesaw, GA 30144.

Device Description: The Endo Illuminator 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 Endo Illuminators 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. Tru Light Endoilluminator and the Grieshaber & Co. Disposable Standard Light Pipe are substantially equivalent since they both are used to 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 handle is made of Delrin, 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.

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 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.