

K960007

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**Premarket Notification
Storz Instrument Company**

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The following information is submitted in accordance with the requirements of 21 CFR 807.92:

Contact Person: Audrey Swearingen, Regulatory Affairs Associate

Date Prepared: December 29, 1995

Proprietary Names: Storz MVS 1011A Fiberoptic Endoilluminator.

Common/Usual Names: Fiberoptic Lightpipe

Classification Name: Illuminator, Fiberoptic, Surgical Field; 79(HBI).

Device Description/Intended Use: The MVS 1011A is intended to be used as an accessory to the Storz PREMIERE® and Storz DAISY™ Microsurgical Systems, as a light source to facilitate viewing of the posterior segment of the eye during ophthalmic surgical procedures. The device consists of an optical fiber encased in plastic tubing; a molded nylon proximal end which connects the device to the microsurgical unit; and a molded acetal distal end, from which protrudes the fiberoptic enclosed within a stainless steel housing. The stainless steel tip, which is the point of light emission, is covered by a plastic protective sleeve that attaches to the molded distal end, and which is removed prior to use of the endoilluminator.

Predicate Device: The Storz MVS 1011A Fiberoptic Endoilluminator is substantially equivalent to its predecessor, the Storz MVS 1011 Fiberoptic Endoilluminator (K854587).

Predicate Comparison: A chart comparing the Storz MVS 1011A with the Storz MVS 1011, showing substantial equivalence, is attached.

Submitted by:

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Storz MVS 1011A Fiberoptic Endoilluminator

Device Comparison Chart

Device Characteristic	Storz MVS 1011A Fiberoptic Endoilluminator	Storz MVS 1011 Fiberoptic Endoilluminator
Intended Use	Light source for posterior ophthalmic surgery	Light source for posterior ophthalmic surgery
Recommended Microsurgical System	Storz PREMIERE® and Storz DAISY™	Storz PREMIERE® and Storz DAISY™
Device Components	Molded distal and proximal ends, polymer optical fiber, stainless steel tubing, epoxy, tip protector	Molded distal and proximal ends, polymer optical fiber, stainless steel tubing, epoxy, tip protector
Total Device Length	74 inches	74 inches
Tip Protector Description	Molded, vented plastic; 2.75 inch length	Silicone tubing; 3.0 inch length
Provided Sterile?	Yes	Yes
Intended to be Reusable?	No	No
Device Packaging	Double pouch	Single pouch
Performance Specification?	Yes	No