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K954816

**Premarket Notification
STORZ Instrument Company**

510(k) SUMMARY OF SAFETY AND EFFICACY

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

Contact Person: Manager, Regulatory Affairs

Date Prepared: October 16, 1995

Proprietary Names: STORZ DP4801 Basic Posterior Vitrectomy Pack; STORZ DP4800 Deluxe Posterior Vitrectomy Pack; STORZ Basic Posterior Vitrectomy Pack with Variable Port Cutter.

Common/Usual Name: Ophthalmic surgical system accessory packs for posterior Vitrectomy

Classification Name: Instrument, vitreous cutting and aspirating, AC-powered (86HQE)

Device Description/Intended Use: The STORZ DP4801, DP4800, and DP4801VP surgical accessory packs contain a vitrectomy probe and attached tubing set to be used in conjunction with the STORZ PREMIERE® or DAISY® Microsurgical Systems in the performance of posterior vitrectomy.

Predicate Device: The STORZ DP4801, DP4800, and DP4801VP are substantially equivalent to the STORZ MVS-3201, DP4400 and DP4400VP anterior vitrectomy packs (K953575).

Predicate Comparison: A chart comparing the STORZ DP4801, DP4800, and DP4801VP posterior vitrectomy packs to the predicate device, demonstrating substantial equivalence, is attached.

Submitted by:

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DEVICE COMPARISON CHART

DEVICE CHARACTERISTIC	Storz DP4801 PACK	Storz DP4800 PACK	Storz DP4801VP PACK	PREDICATE DEVICES: Storz MVS3201 PACK Storz DP4400 PACK Storz DP4400VP PACK
Pack Contents	Vitrectomy Probe with Tube Set and Collection Cassette	Vitrectomy Probe with Tube Set, Collection Cassette plus Deluxe Accessories	Vitrectomy Probe with Tube Set and Collection Cassette	Vitrectomy Probe with Tube Set
Indication For Use	Posterior Vitrectomy	Posterior Vitrectomy	Posterior Vitrectomy	Anterior Vitrectomy
Ophthalmic Surgical System to be Used	STORZ PREMIERE® and DAISY® Systems	STORZ PREMIERE® and DAISY® Systems	STORZ PREMIERE® and DAISY® Systems	STORZ PREMIERE®, Protegé, and DAISY® Systems
Probe Cutting Mechanism Type	Guillotine	Guillotine	Guillotine	Guillotine
Probe Drive Mechanism Type	Pneumatic	Pneumatic	Pneumatic	Pneumatic
Does Probe Cutter Open When Turned Off As A Safety Measure?	YES	YES	YES	YES
Probe Needle Size	20 Gauge	20 Gauge	20 Gauge	20 Gauge
Patient Contact Materials	Type 304 Stainless Steel	Type 304 Stainless Steel	Type 304 Stainless Steel	Type 304 Stainless Steel
Instructions For Use Included In Pack?	YES	YES	YES	YES

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DEVICE COMPARISON CHART

DEVICE CHARACTERISTIC	Storz DP4801 PACK	Storz DP4800 PACK	Storz DP4801VP PACK	PREDICATE DEVICES: Storz MVS3201 PACK Storz DP4400 PACK Storz DP4400VP PACK
Labeled For Single Patient Use Only?	YES	YES	YES	YES
Labeled Per 21CFR §801.109(b)?	YES	YES	YES	YES
Provided Sterile?	YES	YES	YES	YES
Packaging	PETG Tray with TYVEK Lid	PETG Tray with TYVEK Lid	PETG Tray with TYVEK Lid	PETG Tray with TYVEK Lid

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