

K961831



AUG 6 1996

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: Regulatory Affairs Associate

Date Prepared: May 9, 1996

Proprietary Name: Storz DP5200 Irrigation Administration Set Pack.

Common/Usual Name: Microsurgical system accessory pack for delivery of irrigation fluid during ophthalmic surgical procedures.

Classification Name: System, Phacofragmentation (86 HQC).

Device Description/Intended Use: The Storz DP5200 is intended to be used as an accessory to the Storz DAISY® (K854508), Storz Protégé® (K921758 and K950114) and Storz PREMIERE® (K894278, K921460, K946227) Microsurgical Systems as a pathway for delivery of irrigation fluid from the irrigation reservoir, to the surgical handpiece irrigation line, during ophthalmic surgical procedures.

Predicate Devices: The modified Storz DP5200 is substantially equivalent to the Storz existing DP5200 Ambulatory Surgery Center (ASC) Irrigation Administration Set Pack (K894278, K921758) and to the Storz DP4310 Deluxe Phaco Pack (K955901).

Predicate Comparison: A chart comparing the Storz DP5200 to the predicate devices, demonstrating substantial equivalence, is attached.

Submitted by:

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DEVICE COMPARISON CHART

Storz DP5200 Irrigation Administration Set Pack

Device	Storz DP5200, modified	Storz DP5200, existing	Storz DP4310
Intended Use	Delivery of Irrigation Fluid during Ophthalmic Surgical Procedures	Delivery of Irrigation Fluid during Ophthalmic Surgical Procedures	Delivery of Irrigation Fluid and Removal of Aspirant during Ophthalmic Surgical Procedures
Pack Components	Irrigation Administration Set, Instruction Sheet	Irrigation Administration Set	Irrigation Administration Set, I/A Tubing, I/A test Chamber, Tube Stopper, Irrigation Sleeve, Collection Cassette, Mayo Arm Drape, Auxillary Drape, Needle Wrench, Luer cap, Instrucion Sheet
Recommended Systems	Storz Protegé®, PREMIERE®, and DAISY® Microsurgical Systems	Storz Protegé®, PREMIERE®, and DAISY® Microsurgical Systems	Storz Protegé®, PREMIERE®, and DAISY® Microsurgical Systems
Single Patient Use?	Yes	Yes	Yes
Provided Sterile?	Yes	Yes	Yes
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation
Packaging	Tyvek® and PET/PE Pouch	Tyvek® and PET/PE Pouch	High impact Polystyrene Tray with Tyvek Lid