

K961874



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 DP5100 Anterior Collection Cassette Pack

Common/Usual Name: Ophthalmic microsurgical system accessory pack for anterior segment surgical procedures.

Classification Name: System, Phacofragmentation (86 HQC).

Device Description/Intended Use: The Storz DP5100 surgical accessory pack contains a single collection cassette. This component is intended to be used as an accessory to the Storz DAISY® (K854508), Storz Protegé® (K921758 and K950114) and Storz PREMIERE® (K894278, K921460, K946227) Ophthalmic Microsurgical Systems as a reservoir for aspirated fluid and tissue collected during anterior segment ophthalmic surgical procedures.

Predicate Device: The modified Storz DP5100 is substantially equivalent to the existing Storz DP5100 Ambulatory Surgery Center (ASC) Collection Cassette Pack (K894278, K921758), and to the Storz DP4101 Basic Irrigation / Aspiration Pack (K953078).

Predicate Comparison: A chart comparing the Storz DP5100, as modified, to the predicate devices, demonstrating substantial equivalence, is attached.

Submitted by:


Audrey Swearingen
Storz Instrument Company

DEVICE COMPARISON CHART

Storz DP5100 Anterior Collection Cassette Pack

Device	Storz DP5100, modified	Storz DP5100, existing	Storz DP4101
Intended Use	Collection of Aspirant during Anterior Segment Ophthalmic Surgery	Collection of Aspirant during Anterior Segment Ophthalmic Surgery	Delivery of Irrigant and Collection of Aspirant during Anterior Segment Ophthalmic Surgery
Components	Anterior Collection Cassette, Instruction Sheet	Anterior Collection Cassette	I/A Tubing, Test Chamber, Anterior Collection Cassette, Instruction Sheet
Single Patient Use?	Yes	Yes	Yes
Cassette Material	Phillips K-Resin®	LEXAN™	Phillips K-Resin®
Provided Sterile?	Yes	Yes	Yes
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation
Packaging	Tyvek® and PET/PE Pouch, Six pouches per Box	Tyvek® and PET/PE Pouch, Six Pouches per Box	High-impact Polystyrene Tray With Tyvek® Lid, Six Packs per Box

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