



MAR 28 1995

Premarket Notification  
Storz Instrument Company

K955901

510(k) SUMMARY OF SAFETY AND EFFICACY

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 28, 1995

**Proprietary Name:** STORZ DP4310 Deluxe Phaco Pack Without Reflux.

**Common/Usual Name:** Ophthalmic surgical system accessory pack for phacoemulsification.

**Classification Name:** System, Phacofragmentation (86 HQC).

**Device Description/Intended Use:** The STORZ DP4310 surgical accessory pack contains an auxiliary drape (K934445), a Mayo arm drape, an irrigation administration tube assembly, a collection cassette (K953078), and an irrigation/aspiration (I/A) tube assembly. Other components included are a pair of I/A test chambers, a pair of infusion sleeves, a tube stopper, a male Luer cap, and a needle wrench. These components are to be used in conjunction with the STORZ Protegé® (K921758 and K950114), PREMIERE® (K894278, K921460, and K946227) or DAISY® (K854508) Microsurgical Systems in the performance of phacoemulsification.

Phacoemulsification involves the ultrasonic disintegration of the opacified crystalline lens (cataract) from the eye. This process is accomplished by means of an electronically driven ultrasonic handpiece which 1) emulsifies the lens; 2) facilitates the irrigation of the anterior chamber; and 3) facilitates the aspiration of the emulsified lens material and irrigant from the eye. The Storz DP4310 Pack provides the accessories necessary to enable use of the Storz Phacoemulsification Handpieces (K935926) with the above Storz microsurgical systems.

**Predicate Device:** The Storz DP4310 is substantially equivalent to the Storz Universal I/A and Phacoemulsification Pack (K882240).

**Predicate Comparison:** A chart comparing the Storz DP4310 Deluxe Phaco Pack

Without Reflux to the predicate device, demonstrating substantial equivalence, is attached.

**Submitted by:**

A handwritten signature in cursive script that reads "Audrey Swearingen".

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## DEVICE COMPARISON CHART

DEVICE CHARACTERISTIC	STORZ DP4310	STORZ UNIVERSAL I/A PACK
Pack Contents	Aux drape, Arm Drape, Collection Cassette, I/A Tubing, Test Chambers, Infusion Sleeves, Stopper, Cap, Wrench	Collection Cassette, I/A Tubing, Test Chamber
Indication for Use	Irrigation/Aspiration and Phacoemulsification	Irrigation/Aspiration and Phacoemulsification
Applicable Ophthalmic Microsurgical System	Storz DAISY <sup>®</sup> , PREMIERE <sup>®</sup> , and Protegé <sup>®</sup> Systems	Storz DAISY <sup>®</sup> , PREMIERE <sup>®</sup> and Protegé <sup>®</sup> Systems
Patient Contact Material	Medical Grade Silicone	None
Instructions for Use Included in Each Pack?	YES	YES
Labeled Per 21CFR §801.109?	YES	YES
Labeled For Single Patient Use?	YES	NO
Provided Sterile?	YES	NO
Packaging	PETG Tray with TYVEK Lid	Polybag