



AUG 23 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 31, 1996

Proprietary Name: Storz D4600 Air Exchange Line Pack.

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

Classification Name: System, Phacofragmentation (86 HQC).

Device Description/Intended Use: The Storz D4600 is intended to be used as an accessory to the Storz PREMIERE® (K894278, K921460, K946227) or Storz DAISY® (K854508) Microsurgical Systems for use in air and fluid exchange during posterior segment ophthalmic surgical procedures. The D4600 Air Exchange Line provides the initial pathway through which air generated by the microsurgical system is routed into the posterior chamber of the eye.

Predicate Device: The proposed Storz D4600 Air Exchange Line Pack is substantially equivalent to the existing Storz D4600 Air Exchange Line Pack (K894278), and to the Intek International, Inc. TR-9006-11 Air Delivery Tubing System (K832761).

Predicate Comparison: A chart comparing the Storz D4600 to the predicate devices, demonstrating substantial equivalence, is attached.

Submitted by:

Audrey Swearingen
Storz Instrument Company
3365 Tree Court Industrial Blvd.
St. Louis, MO 63122
Ph. 314/225-5051

DEVICE COMPARISON CHART

Storz D4600 Air Exchange Line Pack

Device	Storz D4600, modified	Storz D4600, existing	Intek International TR9006-11
Intended Use	To deliver air to the eye during posterior ophthalmic surgical procedures	To deliver air to the eye during posterior ophthalmic surgical procedures	To deliver air to the eye during ophthalmic surgical procedures
Recommended System	Storz PREMIERE® or Storz Daisy™ Microsurgical Systems	Storz PREMIERE® or Storz Daisy™ Microsurgical Systems	Escalon™ CFAE-40 Air/Fluid Exchange Pump
Instructions For Use Included?	Yes	No	Unknown
Single Patient Use?	Yes	Yes	Yes
Provided Sterile?	Yes	Yes	Yes
Sterilization Method	Gamma Irradiation	Gamma Irradiation	Unknown
Packaging	Singly in Tyvek® and PET/PE Pouch, Ten pouches per Box	Singly in Tyvek® and PET/PE Pouch, Ten pouches per Box	Unknown package type, Ten units per Box