

K960024



Premarket Notification
STORZ Instrument Company

SEP 20 1996

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

Contact Person: Manager, Regulatory Affairs

Date Prepared: December 28, 1995

Proprietary Names: Storz D7120 Phaco Handpiece Maintenance Kit and Storz D7125 Needle Wrench.

Common/Usual Name: Ophthalmic microsurgical system accessories for phacoemulsification.

Classification Name: System, Phacofragmentation (86 HQC).

Device Description/Intended Use: The Storz D7120 Phaco Handpiece Maintenance Kit and the Storz D7125 Needle Wrench are intended to be used as accessories to Storz DAISY® (K854508), Storz Protegé® (K921758 and K950114), and PREMIERE® (K894278, K921460, and K946227) Microsurgical Systems for use in performing phacoemulsification. The D7120 contains an assortment of tools useful in cleaning and maintaining the Phacoemulsification Handpiece (K935926) and the D7125 is an individual tool used in the assembly and disassembly of the handpiece.

Predicate Device: The Storz D7120 and D7125 are substantially equivalent to similar cleaning and maintenance tools recommended by manuals for the Alcon Series 20000™ LEGACY™ (K952213) and the AMO® Prestige™ Advanced Cataract Extraction System™ (K number unknown) systems.

Predicate Comparison: A chart comparing the Storz D7120 and D7125 to the predicate devices, demonstrating substantial equivalence, is attached.

Submitted by:

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

DEVICE COMPARISON CHART

| Device Characteristic | AMO® Prestige™ | SERIES 20000® LEGACY™ | Storz D7120 and D7125 |
|---|--|--|---|
| Intended Use | Cleaning Ultrasonic Handpiece Immediately After Use | Cleaning Ultrasonic Handpiece Immediately After Use | Cleaning Ultrasonic Handpiece Immediately After Use |
| Tools Recommended / Included | Recommended: Syringe, Fluidics Connectors, Tip Wrench | Recommended: Syringe, Fluidics Connectors, Tip Wrench | Included: Syringe, Stopcock Fluidics Connectors, Needle Wrench, Aspirator Brush |
| Instrument Type | Phacoemulsification Handpiece | Phacoemulsification Handpiece | Phacoemulsification Handpiece |
| Tools Provided Sterile? | No | No | No |
| Tools Commonly Available Or Available From Supplier? | Yes | Yes | Yes |