

K 960061



SEP 18 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: Audrey Swearingen, Regulatory Affairs Associate

Date Prepared: January 3, 1996

Proprietary Names: Storz D7108 Microscissors Handpiece and Storz D7106 Microscissors Drive Tube.

Common/Usual Names: Microscissors handpiece and drive tube

Classification Name: Vitreous aspiration and cutting instrument, AC-powered, (86HQE).

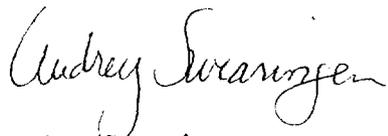
Device Description/Intended Use: The Storz D7108 Microscissors Handpiece is a reusable, electrically powered, pneumatic handpiece that is used to operate a variety of detachable microscissors. A selected microscissors attachment screws on to the tip of the D7108 Microscissors Handpiece. The D7108 handpiece attaches to the Storz D7106 Microscissors Drive Tube, which in turn connects to the Storz PREMIERE® or the Storz DAISY™ Ophthalmic Microsurgical System. As the "Scissors" function of the microsurgical system is activated, the piston inside the D7108 handpiece is driven forward and backward by air pressure, causing the blades of the attached microscissors to open and close rapidly. The handpiece also has a manual over-ride lever near the tip of the handpiece that allows the physician to manually operate the scissors without requiring external power.

The D7108 handpiece, as connected to the D7106 drive tube and detachable microscissors, is intended to be used with the Storz PREMIERE® or Storz DAISY™ Microsurgical Systems to cut intraocular tissue in the posterior segment of the eye during ophthalmic surgical procedures.

Predicate Device: The Storz D7108 Microscissors Handpiece and D7106 Microscissors Drive Tube, as used together, are substantially equivalent to the Escalon™ Trek Medical Vertical Automated Scissors.

Predicate Comparison: A chart comparing the Storz D7108 and D7106 to the predicate device, demonstration substantial equivalence, is attached.

Submitted By:



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Storz D7108 Microscissors Handpiece / Storz D7106 Microscissors Drive Tube

DEVICE COMPARISON CHART

Device Characteristic	Storz D7108 and D7106	Escalon™ Trek Medical Vertical Automated Scissors
Intended Use	To be attached to microscissors for cutting of posterior intraocular tissue.	Cutting of posterior intraocular tissue.
Components	D7108 Microscissor Handpiece and D7106 Microscissor Drive Tube	Microscissor handpiece, microscissors, and drive tube.
Recommended Microsurgical System	Storz PREMIERE® and Storz DAISY™	Storz PREMIERE®, Alcon STTO VM™, MVS XII™, and MVS XX™.
Compatible with single and multi cut modes?	Yes	Yes
Reusable?	Yes	Yes
Manual operation capability?	Yes	Unknown