



FEB - 3 1997

Premarket Notification
Storz Instrument Company

K964743

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

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Date Prepared: January 9, 1997.

Proprietary Name: Storz E8010 ErgoTec™/Premiere® Adaptor.

Common/Usual Name: Adaptor for ophthalmic microscissors driver handpiece and interchangeable instrument tips.

Classification Name: Instrument, vitreous cutting and aspirating (86HQE).

Device Description/Intended Use: The Storz E8010 ErgoTec™/Premiere® Adaptor is a new device accessory designed to adapt the Storz ErgoTec™ Vitreoretinal Instrument Tips to the Storz D7108 Microscissors Handpiece for general use in posterior segment vitreoretinal ophthalmic surgery. The Storz E8010 ErgoTec™/Premiere® Adaptor is composed of stainless steel and serves to allow connection of the existing Storz D7108 Microscissors Handpiece to the existing Storz ErgoTec™ Vitreoretinal Instrument Tips. An illustration of the the Storz E8010 ErgoTec™/Premiere® Adaptor is included in the device instructions which are attached.

Predicate Device: The Storz D7108 Microscissors Handpiece, as it utilizes the new Storz E8010 ErgoTec™/Premiere® Adaptor and Storz ErgoTec Instrument Tips, is similar in design, function, and composition to the Storz CX7100 and CX7150 Microscissors Handpieces (K961310) and the existing Storz Microscissors Handpiece (K960061).

Predicate Comparison: A chart comparing characteristics of the Storz D7108 Microscissors Handpiece, as it utilizes the new Storz E8010 ErgoTec™/Premiere® Adaptor and Storz ErgoTec Instrument Tips, to those of the predicate devices, is attached.

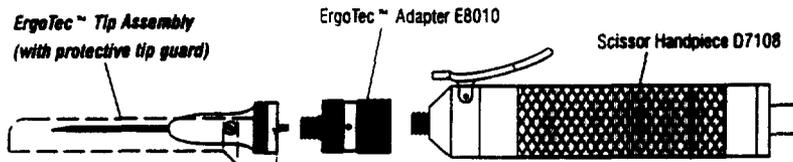
Submitted by:

Patrick G. Balsmann
Regulatory Affairs



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ErgoTec™/Premiere® Adapter – E8010 User Instructions

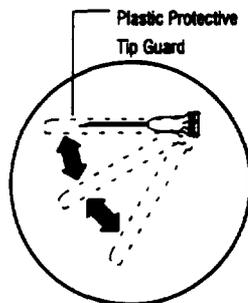


The Storz E8010 ErgoTec™/Premiere® Adaptor allows the ErgoTec™ Vitreoretinal Instrument System tips to be used with the Storz D7108 Microscissors Handpiece. The adaptor features an anterior rotation knob which allows the tip to be adjusted into optimal alignment.

NOTE: Refer to the Premiere® Microsurgical System owner's manual for instructions on use of the Storz D7108 Microscissors Handpiece.

Preparation for Use

- Hold the handpiece firmly and thread the adaptor to the handpiece by grasping the posterior end of the adaptor and turning it clockwise onto the handpiece until secure.
- With the plastic protective tip guard in place, hold the rotation knob of the adaptor firmly and securely attach the tip to the adaptor/handpiece assembly by threading the tip clockwise onto the assembly.
- Remove the protective tip guard by grasping the guard at the tip end and pulling it downward from the tip toward the adaptor/handpiece assembly.



Disassembly of Instrument

- Reinstall the protective tip guard in opposite manner of removal. Hold the rotation knob of the adaptor firmly and unscrew the tip by turning counterclockwise being careful to protect the tip from damage.
- Hold the handpiece firmly and unscrew the adaptor by grasping the posterior end and turning counterclockwise.

Cleaning and Sterilization Instructions

- For the ErgoTec™ Tip, follow the cleaning and sterilization instructions which came with the tip.
- The adaptor should be removed from the handpiece for cleaning.
- Clean outer surfaces with mild detergent solution and water.
- Thoroughly rinse with warm (30–40°C) distilled or deionized water.
- The adaptor should be installed on the handpiece for sterilization.

The minimum requirements for sterilization are:

- Standard Gravity Steam Sterilization (Preferred method).** Place the handpiece in a clean open tray, wrapped or unwrapped. Sterilize for 30 minutes at 121° C. (250° F).
- Flash Sterilization.** Place the unwrapped handpiece in a clean open tray. Sterilize for 10 minutes at 132° C. (270° F).
- High Vacuum Sterilization.** Place the wrapped handpiece in a clean open tray. Sterilize for a minimum of 3 minutes at 134° C. –0/+3°.

CAUTION: Allow the adaptor/handpiece assembly to cool at least 20 minutes before handling.

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**Storz E8010 ErgoTec™/Premiere® Adaptor
Device Comparison Chart**

Device Characteristic	Storz D7108 Microscissor HP (with new Storz ErgoTec™/Premiere® Adaptor)	Storz D7108 Microscissor HP (without Storz ErgoTec™/Premiere® Adaptor)	Storz CX7100 & CX7150 Microscissors HP's
510(k) #	Current. K964743	# K960061	# K961310
Intended Use	Cutting and manipulation of posterior intraocular tissue.	Cutting and manipulation of posterior intraocular tissue.	Cutting and manipulation of posterior intraocular tissue.
Recommended Microsurgical System	Storz Premiere® Microsurgical System.	Storz Premiere® Microsurgical System.	Storz Millennium™ Microsurgical System.
System Components	Storz D7108 Microscissor Handpiece; Storz D7106 Microscissor Drive Tube; Storz E8010 ErgoTec™/Premiere® Adaptor; Storz ErgoTec™ Vitreoretinal Instrument Tips.	Storz D7108 Microscissor Handpiece; Storz D7106 Microscissor Drive Tube; Grieshaber Microscissors Tips.	Storz CX7100 Vertical Cut Handpiece; Storz CX7150 Proportional Cut Handpiece; Storz ErgoTec™ Vitreoretinal Instrument Tips.
Microscissor Activation Mechanism	Pneumatic.	Pneumatic.	Electrical.
Detachable Tips?	Yes.	Yes.	Yes.
Rotatable Tips?	Yes.	Yes.	Yes.
Reusable Tips?	Yes.	Yes.	Yes.
Tip Materials?	420 Stainless steel.	Stainless steel.	420 Stainless steel.
Compatible With Single & Multi-Cut Modes?	Yes.	Yes.	Yes.
Footpedal Control?	Yes.	Yes.	Yes.

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