



AUG 29 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:** Manager, Regulatory Affairs

**Date Prepared:** December 28, 1995

**Proprietary Names:** STORZ D7116 Microvit® Vitrectomy Cutter Extension.

**Common/Usual Name:** Ophthalmic surgical system accessory grip extension for vitrectomy cutter.

**Classification Name:** Instrument, vitreous cutting and aspirating, AC powered (95HQC).

**Device Description/Intended Use:** The Storz device is intended to be used as an accessory to the Storz Microvit® Vitrectomy Cutter to provide a snap-on grip extension for the cutter to facilitate manipulation of the instrument. The D7116 does not affect the functioning of the cutter. A drawing of the the D7116 and a drawing of the cutter are attached as Exhibits 1 and 2 respectively.

**Predicate Device:** The Storz D7116 is substantially equivalent to a Storz MVS-3201 Vitrectomy Probe Pack (K953575).

**Predicate Comparison:** A chart comparing the Storz D7116 to the predicate device, demonstrating substantial equivalence, is attached.

**Submitted by:**

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## DEVICE COMPARISON CHART

<b>Device Characteristic</b>	<b>Storz MVS-3201 Vitrectomy Probe</b>	<b>Vitrectomy Probe With D7116 Extension</b>
<b>Rear Aspect Annular Grip?</b>	Yes	Yes
<b>Indication for Use</b>	Vitrectomy, Surgeon's Preferred Technique	Vitrectomy, Surgeon's Preferred Technique
<b>Alterations to Probe Required?</b>	No	No