

MAR 23 1998

**Storz Millennium™ High Speed Vitrectomy System
Premarket Notification**

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

Contact Person: Gary Rauvola, Regulatory Affairs Group Manager
Bausch & Lomb Surgical, Storz Products
3365 Tree Court Industrial Blvd.
St. Louis, MO 63122-6694
Phone: (314) 225- 5051, ext. 5340.

Date Prepared: February 4, 1998

Proprietary Name: Storz Millennium™ High Speed Vitrectomy System

Common/Usual Name: Automated Vitrectomy Device

Classification Name: Vitreous Aspiration & Cutting Instrument, 86 HQE; 21CFR §886.4150.

Device Description/Intended Use: The Storz Millennium™ High Speed Vitrectomy System is intended for the aspiration of vitreous matter from the eye during ophthalmic vitrectomy surgery. The system consists of the Storz CX5800 Millennium™ System High Speed Vitrectomy module used with the Storz Millennium™ Microsurgical System, Storz CX5810 High Speed Vitrectomy handpiece, and the Storz CX4804 High Speed Vitrectomy single use disposable pack.

Predicate Devices: The Storz CX5800 Millennium™ System High Speed Vitrectomy module is substantially equivalent in design and function to the Storz Millennium™ Microsurgical System (K961310), Promex Vitrectomy System (K961078), Scieran Technologies VIT Commander System (K961738), and the Alcon Accurus™ Vitreoretinal Surgical System. The Storz CX5810 Millennium™ High Speed Vitrectomy handpiece is substantially equivalent to the Storz MicroVit Vitrectomy Probe (K954816 and K961310), Promex Vitrectomy handpiece (K961078), Alcon Accurus InnoVit Probe, and the Scieran Vit Commander System handpiece (K961738). The Storz CX4804 High Speed Vitrectomy pack is similar in design, composition, and function to the Storz DP4801 Vitrectomy Probe pack (K954816 and K961310), the Promex vitrectomy cutter pack (K961078), and the Alcon Accurus Total Plus Pak.

Predicate Comparisons: Charts comparing characteristics of the Storz CX5800 Millennium™ High Speed Vitrectomy module, Storz CX5810 Millennium™ High Speed Vitrectomy handpiece, and the Storz CX4804 pack to those of the predicate devices are attached.

Submitted by:



Gary Rauvola
Regulatory Affairs Group Manager

**Storz CX5800 Millennium™ High Speed Vitrectomy Module
Device Comparison Chart**

Device Description	Storz CX5800 High Speed Vitrectomy Module	Storz Millennium™ Microsurgical System	Alcon Accurus™ Vitreoretinal Surgical System	Promex Vitrectomy System	Scieran Technologies Vit Commander System
510(k)	current	K961310	unknown	K961078	K961738
Intended Use	Posterior segment ophthalmic surgery.	Anterior & posterior segment ophthalmic surgery.	Posterior segment ophthalmic surgery.	Posterior segment ophthalmic surgery.	Posterior segment ophthalmic surgery.
Modular Design	Yes.	Yes.	No.	No.	Yes.
Ophthalmic Features	Vitrectomy.	Viscous fluid injection/aspiration, Irrigation/aspiration, phacoemulsification / fragmentation, vitrectomy, scissors, bipolar, illumination, & IOP control.	Viscous fluid injection/aspiration, Irrigation/aspiration, fragmentation, vitrectomy, scissors, bipolar, illumination, & IOP control.	Vitrectomy, aspiration.	Irrigation/aspiration, vitrectomy, bipolar.
Programmable For Multiple Surgeons	Yes.	Yes.	Yes.	No.	No.
Disposable Accessories	Yes.	Yes.	Yes.	Yes.	Yes.
User Interface	Foot pedal & touch screen.	Foot pedal & touch screen.	Foot pedal & touch screen.	Foot pedal & control knobs.	Foot pedal & control knobs.
Foot Controller - Dual Linear	Yes.	Yes.	No.	No.	No.

**Storz CX5810 High Speed Vitrectomy Handpiece
Device Comparison Chart**

Device Description	Storz CX5810 High Speed Vitrectomy Handpiece	Storz MicroVit® Vitrectomy Probe	Alcon Accurus™ InnoVit™ Probe	Promex Vitrectomy System	Scieran Technologies Vit Commander System
510(k)		K954816 K961310	unknown	K961078	K961738
Intended Use	Posterior Vitreous Removal	Posterior Vitreous Removal	Posterior Vitreous Removal	Posterior Vitreous Removal	Posterior Vitreous Removal
Cuts Per Minute	400-1500 cpm	30 - 750 cpm	100-1200 cpm	up to 2000 cpm	400-2500 cpm
Sterilization	Autoclavable handpiece with disposable tip	Single use Disposable	Single use Disposable	Autoclavable handpiece with disposable tip	Autoclavable handpiece with disposable tip
Handpiece Body	Anodized aluminum	Plastic	Plastic	Stainless steel and aluminum	Titanium
Type of Handpiece Drive	Electric	Pneumatic	Pneumatic	Electric	Electric
Associated Aspiration system	Venturi	Venturi	Venturi	Venturi	Diaphragm
Cutting Action	Guillotine	Guillotine	Guillotine	Guillotine	Guillotine

**Storz CX4804 High Speed Vit Cutter Pack
Device Comparison Chart**

Device Description	Storz CX4804 High Speed Vit Cutter Pack	Storz DP4801 Vitrectomy Probe Pack	Alcon Accurus™ Total Plus™ Pak	Promex Pack
510(k)		K954816 K961310	unknown	K961078
Pack Components	High speed vitrectomy cutter with aspiration tubing.	Vit cutter, aspiration tubing, collection cassette.	Cassette with drain bag, vitrectomy probe, fiber optic illuminator probe, aspiration tubing, infusion spike, infusion cannula.	High speed vitrectomy cutter with aspiration tubing.
Applicable Ophthalmic Surgical Unit	Storz Millennium Microsurgical System.	Storz Millennium Microsurgical System. Storz Premiere Microsurgical System.	Alcon Accurus Vitreoretinal Surgical System.	Promex Vitrectomy System.
Provided Sterile	Yes.	Yes.	Yes.	Yes.
Labeled For Single Patient Use	Yes.	Yes.	Yes.	Yes.
Patient Contact Material	AISI 304 stainless steel with anti-reflective etch.	AISI 304 stainless steel.	Stainless steel	AISI 304 stainless steel.
Packaging	Sealed Tyvek trays. Six trays/box.	Sealed Tyvek trays. Six trays/box.	Unknown	Unknown



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Gary Rauvola
Regulatory Affairs Group Manager
Bausch & Lomb Surgical, Storz Products
3365 Tree Court Industrial Blvd.
St. Louis, MO 63122-6694

Re: K980488
Trade Name: Storz Millennium Microsurgical System High Speed Vitrectomy
Regulatory Class: II
Product Code: 86 HQE
Dated: February 4, 1998
Received: February 9, 1998

Dear Mr. Rauvola:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**Storz Millennium™ High Speed Vitrectomy System
Premarket Notification**

INDICATIONS FOR USE

Device Name: Storz Millennium™ High Speed Vitrectomy System

Indications for Use: The Storz Millennium™ High Speed Vitrectomy System is a new device intended for removal of vitreous matter from the posterior vitreous cavity during ophthalmic vitrectomy surgery. The Storz high speed vitrectomy system consists of the Storz CX5800 module to be used with the Storz Millennium™ Microsurgical System, Storz CX5810 handpiece, and the Storz CX4804 sterile single use accessory pack.

Prescription Use Over the Counter Use

Dennis L. M. J. Carthy

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K960488