K972664

storz®

Storz Millennium™ Viscous Fluid System
Premarket Notification

OCT 10 1997

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

Contact Person: Patrick G. Balsmann, Regulatory Affairs Associate
Storz, 3365 Tree Court Industrial Bldv., St. Louis, MO 63122-6694
Phone: (314) 225- 5051, ext. 5538.

Date Prepared: July 15, 1997

Proprietary Name: Storz Millennium™ Viscous Fluid System

Common/Usual Name: Viscous Fluid Injection/Aspiration System(s).

Classification Name: Infusion Pump, 86 MRH; 21CFR §880.5725.

Device Description/Intended Use: The Storz Millennium™ Viscous Fluid System is intended for the injection and aspiration of viscous fluids into and out of the eye during posterior ophthalmic vitreoretinal surgery. The system is designed to inject and aspirate viscous fluids, such as silicone oil which act as a tamponade in fixating large retinal tears and detachments. The Storz viscous fluid system consists of the Storz CX5700 Millennium™ Viscous Fluid System Module and the Storz CX5710 Viscous Fluid Injection Pack. The Storz CX5700 module is a self-contained pump system used as an individual module with the Storz Millennium™ Microsurgical System for the injection and aspiration of viscous fluids. The Storz CX5710 is the disposable accessory pack intended for single use to be used with the Storz viscous fluid module.

Predicate Device: The Storz CX5700 Millennium™ Viscous Fluid System Module is similar in design and function to the Storz Millennium™ Microsurgical System (K961310), Escalon® Viscous Fluid System (K963434), the Richard James Viscous Fluid Transfer System (K902835), and the Alcon Accurus™ Vitreoretinal Surgical System. The Storz CX5710 Viscous Fluid Injection Pack is similar in design, composition, and function to the Escalon® Fluid Delivery Pack (K963434.)

Predicate Comparison: A chart comparing characteristics of the Storz CX5700 Millennium™ Viscous Fluid System Module and the Storz CX5710 Viscous Fluid Injection Pack to those of the predicate devices is attached.

Submitted by:

Patrick G. Balsmann
Regulatory Affairs

Storz CX5700 Millennium™ Viscous Fluid System Module
Device Comparison Chart

Device Description **510(k)**	**Storz CX5700 Viscous Fluid System** **current**	**Storz Millennium™ Microsurgical System** **K961310**	**Alcon Accurus™ Vitreoretinal Surgical System** **unknown**	**Escalon® Viscous Fluid System** **K963434**	**Richard James Viscous Fluid Transfer System** **K902835**
Intended Use	Posterior segment ophthalmic surgery - injection & aspiration of viscous fluids	Anterior & posterior segment ophthalmic surgery.	Posterior segment ophthalmic surgery.	Posterior ophthalmic surgery - injection & aspiration of viscous fluids.	Posterior ophthalmic surgery - injection & aspiration of viscous fluids.
Modular Design	Yes	Yes.	No.	No.	No.
Ophthalmic Features	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.	Viscous fluid injection/aspiration.	Viscous fluid injection/aspiration.
Programmable For Multiple Surgeons	Yes.	Yes.	Yes.	No.	No.

Storz CX5700 Millennium™ Viscous Fluid System Module
Device Comparison Chart

Device Description **510(k)**	**Storz CX5700 Viscous Fluid System** **current**	**Storz Millennium™ Microsurgical System** **K961310**	**Alcon Accurus™ Vitreoretinal Surgical System** **unknown**	**Escalon® Viscous Fluid System** **K963434**	**Richard James Viscous Fluid Transfer System** **K902835**
Disposable Accessories	Yes.	Yes.	Yes.	Yes.	Yes.
Viscous Fluid User Interface	Foot pedal & touch screen.	Foot pedal & touch screen.	Foot pedal & touch screen.	Foot pedal & control knob.	Foot pedal & control knob.
Foot Controller - Dual Linear	Yes	Yes.	No.	No.	No.
Viscous Fluid Injection, Pressure Range	0 - 70 PSI.	Not Applicable.	0 - 80 PSI.	0 - 70 PSI.	0 - 70 PSI.
Viscous Fluid Injection, Aspiration Range	0 - 600 mmHg.	Not Applicable.	0 - 600 mmHg.	0 - 600 mmHg.	0 - 650 mmHg.

Storz CX5710 Viscous Fluid Injection Pack
Device Comparison Chart

Device Description **510(k)**	**Storz CX5710 Viscous Fluid Injection Pack** **current**	**Escalon® Fluid Delivery Pack** **K963434**
Pack Components	Modified hose barb, tubing, male luer with locking nut, filter, 10cc syringe adaptor, 10cc modified piston, needle/cover assembly, 10cc standard piston, & 10cc syringe assembly.	Hose barb, tubing, male luer with locking nut, filter, 10cc syringe adaptor, 10cc modified piston, needle/cover assembly, 10cc standard piston, & 10cc syringe assembly.
Applicable Ophthalmic Surgical Unit	Storz Millennium™ Microsurgical System	Escalon® Viscous Fluid System
Provided Sterile	Yes	Yes.
Labeled For Single Patient Use	Yes	Yes.
Patient Contact Material	AISI 303 stainless steel.	AISI 303 stainless steel.
Packaging	Sealed Tyvek® pouches. 10 packs/box.	Sealed Tyvek® pouches. 10 packs/box.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 1997

Mr. Patrick G. Balsmann
Domestic Regulatory Affairs Associate
Storz Instrument Company
3365 Tree Ct. Industrial Blvd.
St. Louis, MO 63122-6694

Re: K972664
Trade Name: Storz Millennium™ Viscous Fluid System
Regulatory Class: II
Product Code: 86 MRH
Dated: July 15, 1997
Received: July 16, 1997

Dear Mr. Balsmann:

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.

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™ Viscous Fluid System
Premarket Notification

INDICATIONS FOR USE

Device Name: Storz Millennium™ Viscous Fluid System

Indications for Use: The Storz Millennium™ Viscous Fluid System is a new device intended for the injection and aspiration of viscous fluids into and out of the eye during ophthalmic posterior vitreoretinal surgery. The Storz viscous fluid system consists of the Storz CX5700 module to be used with the Storz Millennium™ Microsurgical System and the Storz CX5710 sterile single use accessory pack.

Ernette T. Boen

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K972664

Prescription Use ✓
(Per 21 CFR 801.109)

014