3365 Tree Court Industrial Blvd
St. Louis, MO USA 63122-6694

314 225 5051
800 338 2020

K993039

JAN - 7 2000

SUMMARY OF SUBSTANTIAL EQUIVALENCE

BAUSCH & LOMB
Surgical

Contact Person: Vanada Johnson, Regulatory Affairs Specialist
Bausch & Lomb Surgical
3365 Tree Court Industrial Blvd.
St. Louis, MO 63122-6694
Phone (636)-226-3182
Fax (636) 226-3030

Date Prepared: September 10, 1999

The Storz Millennium Viscous Fluid Injector system (VFI) is a Class II device in accordance with 21 CFR Section 880.5725. Further, the VFI and its accessories was previously cleared, via the Premarket Notification process and was assigned 510(k) file number K972664 and Classification Code 86 MRH.

The VFI system module (CX5700) is a self-contained pump system used in conjunction with the Storz Millennium™ Microsurgical System (K961310). The Storz Millennium™ Viscous Fluid Injector System (K972664) is intended for the injection of viscous fluids and Balance Salt Solution (BSS) into to eye as well as aspiration of viscous fluids from the eye during ophthalmic posterior vitreoretinal and retinal translocation surgical procedures using the Bausch & Lomb Surgical's disposable, single-use accessories .

The only difference between the proposed vs. the predicate VFI system is the inclusion of administering Balanced Salt Solution used for retinal translocation procedures. The Millennium™ Viscous Fluid Injector System (K972664), in and of itself, will remain unchanged in that there will be no changes to the design, functional characteristics, sterilization method(s), product specifications, or intended use.

Bausch & Lomb Surgical considers the VFI system to be substantially equivalent in design and intended use in comparison to the currently marketed Viscous Fluid Injection System covered by K972664. Further, Bausch & Lomb considers the VFI system similar to the following previously cleared 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.

Submitted by:

Vanada Johnson
Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2000

Ms. Vanada Johnson
Regulatory Affairs Specialist
Bausch & Lomb Surgical
3365 Tree Court Industrial Blvd.
St. Louis, MO 63122-6694

Re: K993039
Trade Name: Viscous Fluid Injector System Module
Regulatory Class: II
Product Code: 86 MRH
Regulation: 880.5725
Dated: December 6, 1999
Received: December 7, 1999

Dear Ms. Johnson:

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

510(K) Number [redacted] K993039

Device Name: Storz Millennium Viscous Fluid System

Indications for Use:

The Storz Millennium™ Viscous Fluid System is intended for the injection of viscous fluids and Balance Salt Solution (BSS) into to eye as well as aspiration of viscous fluids from the eye during ophthalmic posterior vitreoretinal and retinal translocation 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 consisting of an infusion tube set, a syringe, a Cannula and instructions for use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Division Sign-Off) Dennis L. McCarthy

510(k) Number K993039

Bausch & Lomb Surgical