K980100

storz®

JUN 1 1998

Storz DP4210 Venturi Economy Anterior Pack and DP5000 ASC Daypack
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: Patrick G. Balsmann, Regulatory Affairs Associate. (314) 225-5051
STORZ, 3365 Tree Court Industrial Blvd., St. Louis, MO 63122-6694

Date Prepared: January 9, 1998.

Proprietary Name: Storz DP4210 Venturi Economy Anterior Pack and DP5000 ASC Daypack.

Common/Usual Name: Ophthalmic microsurgical system irrigation/aspiration and phacoemulsification accessory packs.

Classification Name: Unit, Phacofragmentation (86HQC).

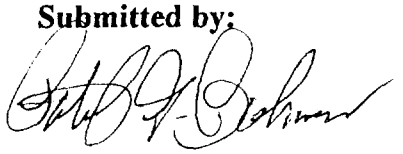
Device Description/Intended Use: The Storz DP4210 Venturi Economy Anterior Pack and DP5000 ASC Daypack are intended to be used as accessory devices with the Storz DAISY® (K854508), PREMIERE® (K894278, K921460 and K946227), Protegé® (K921758 and K950114), and Millennium™ (K961310) Ophthalmic Microsurgical Systems. Both accessory packs facilitate use of Storz phaco handpieces (K935926) and Storz I/A handpieces (K951463) with the above referenced microsurgical systems in various anterior segment ophthalmic surgical procedures, e.g., phacoemulsification and residual cortical material removal following a planned Extracapsular Cataract Extraction.

The Storz DP4210 Venturi Economy Anterior Pack is provided non-sterile and contains reusable components consisting of an anterior collection cassette, I/A tubing set, and I/A test chambers. The Storz DP5000 ASC Daypack is provided sterile and contains both reusable and single use components. The DP5000 reusable items include an anterior collection cassette, I/A test chambers, needle wrench, and infusion sleeve. The DP5000 single use items include an I/A tube assembly and a BSS administration tube assembly.

Predicate Device: The Storz DP4210 Venturi Economy Anterior Pack is substantially equivalent to the Storz DP4210 Universal I/A and Phaco Pack (K882240.) The Storz DP5000 ASC Daypack is substantially equivalent to the Storz DP4210 Universal I/A and Phaco Pack (K882240) and the Storz DP4310 Deluxe Phaco Pack (K955901.)

Predicate Comparison: A chart comparing the Storz DP4210 Venturi Economy Anterior Pack and DP5000 ASC Daypack to their respective predicate devices, demonstrating substantial equivalence, is attached.

Submitted by:



Patrick G. Balsmann
Regulatory Affairs Associate
Storz Instrument Company

Storz DP4210 Venturi Economy Anterior Pack
Device Comparison Chart

Device Characteristic	Storz DP4210 (modified)	Storz DP4210 (existing)
510(k):	Present.	Storz K882240. Referenced as accessory device in Storz DAISY® (K854508), PREMIERE® (K894278, K921460 and K946227), Protegé® (K921758 and K950114), and Millennium™ (K961310) Ophthalmic Microsurgical Systems.
Pack Name:	DP4210 Venturi Economy Anterior Pack	DP4210 Universal I/A and Phaco Pack
Intended Use:	Anterior segment irrigation/ aspiration and phacoemulsification ophthalmic surgical procedures.	Anterior segment irrigation/ aspiration and phacoemulsification ophthalmic surgical procedures.
Individual Pack Components:	(1) Anterior Collection Cassette (1) I/A Tubing Set (2) I/A Test Chamber	(1) Anterior Collection Cassette (1) I/A Tubing Set (2) I/A Test Chamber
Anterior Collection Cassette:	Cylindrical silicone reflux tube.	Rectangular silicone reflux tube.
Reusable Components:	Yes, all components.	Yes, all components.
Limited Reuse:	Not to exceed 20 times.	Not to exceed 20 times.
Pack Provided Sterile:	No.	No.

Storz DP5000 ASC Daypack
Device Comparison Chart

Device Characteristic	Storz DP5000	Storz DP4210	Storz DP4310
510(K):	Referenced as accesory device in Storz DAISY® (K854508), PREMIERE® (K894278, K921460 and K946227), Protegé® (K921758 and K950114), and Millennium™ (K961310) Ophthalmic Microsurgical Systems. Present.	Storz K882240.	Storz K955901.
Pack Name:	DP5000 ASC Daypack.	DP4210 Universal I/A and Phaco Pack	DP4310 Deluxe Phaco Pack.
Intended Use:	Anterior segment irrigation/ aspiration and phacoemulsification ophthalmic surgical procedures.	Anterior segment irrigation/ aspiration and phacoemulsification ophthalmic surgical procedures.	Anterior segment irrigation/ aspiration and phacoemulsification ophthalmic surgical procedures.
Individual Pack Components:	(1) Anterior Collection Cassette (2) I/A Test Chamber (1) Needle Wrench (2) Infusion Sleeve (1) I/A Tube Assembly (1) BSS Administration Tube Assembly	(1) Anterior Collection Cassette (1) I/A Tubing Set (2) I/A Test Chamber	(1) Anterior Collection Cassette (2) I/A Test Chamber (1) Needle Wrench (2) Infusion Sleeve (1) I/A Tube Assembly (1) BSS Administration Tube Assembly (1) Auxiliary Drape (1) Mayo Arm Drape (1) Male Luer Cap (1) Tube Stopper
Reusable Components:	Yes, anterior collection cassette, I/A test chamber, needle wrench, and infusion sleeve.	Yes, all components.	No.
Limited Reuse Components:	Not to exceed 10 times.	Not to exceed 20 times.	Not applicable.
Pack Provided Sterile:	Yes.	No.	Yes.
Pack Sterilization:	Not applicable.	Gamma irradiation.	Gamma irradiation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 1998

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

Re: K980100
Trade Name: Storz DP4210 Venturi Economy Anterior Pack and DP500 ASC Daypack
Regulatory Class: II
Product Code: 86 MSR
Dated: April 24, 1998
Received: April 27, 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.

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 (if known): K980100 Recall

Device Name: DP4210 Venturi Economy Anterior Pack
DP5000 ASC

Indications For Use:

The Storz DP4210 Venturi Economy Anterior Pack and DP5000 ASC Daypack contain replaceable tubings, collection cassettes, needle sleeves, and tip testers for the Storz Daisy®, PREMIERE®, and Millennium™ Ophthalmic Microsurgical Systems which are used in anterior segment ophthalmic surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K980100

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)