



K961310

510(k) Summary of Safety and Effectiveness

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

Submitted by:

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Proprietary Name: This device has been tentatively named the Storz PREMIERE II Microsurgical System. The proprietary name may be changed prior to distribution.

Common/Usual Name: Ophthalmic surgical system for cataract and vitro retinal surgery.

Classification Name: The device system is a Class II ophthalmic microsurgical system, Class II medical device, which is a combination of the following classification names:

1. Phacofragmentation system, 21 CFR §886.4670;
2. Vitreous Aspirating and Cutting Device, 21 CFR §886.4150; and
3. Radiofrequency Electrosurgery cautery Apparatus, 21 CFR §886.4100.

Device Description/ Intended Use: The Storz PREMIERE II is a modular ophthalmic microsurgical system which is designed to be configured by Storz for use in anterior segment surgery only, posterior segment surgery only, or both. The modular design allows user configuration of the system.

The PREMIERE II system is divided into the following functional sections:

1. Computer Unit. This unit will sit upon the PREMIERE II Ophthalmic Unit and is composed of an embedded PC and a display console.

2. **Ophthalmic Unit.** This unit is comprised of a base unit, a power supply module, and up to five selected ophthalmic modules. The base unit is the primary housing for the system ophthalmic instrumentation, and is designed to facilitate front loading and unloading of up to six modules. The power supply module is the power source for the remaining five modules occupying the base unit. The ophthalmic modules are functional units, each of which contain the necessary components to interface the module with the Ophthalmic Base Unit or Ophthalmic Expansion Unit. The ophthalmic modules which will be available at product introduction are:
 - a. Air/Fluid Exchange and Scissors/Forceps module.
 - b. Bipolar Coagulation module.
 - c. Illumination module.
 - d. Irrigation, Scroll Aspiration, and Vitrectomy module.
 - e. Irrigation, Venturi aspiration, and Vitrectomy module.
 - f. Phacoemulsification and Phacofragmentation module.
 - g. Phaco module.
 - h. Frag module.

3. **Peripherals.** The following peripheral devices will be available at product introduction: Instrument Cart with automated IV pole, Ophthalmic Expansion Unit for additional modules, Remote Control Unit, and Foot Control.

New accessory devices to be marketed for use with the Storz PREMIERE II system.

These include the following:

1. CX4310 Deluxe Scroll Phaco Pack.
2. CX4800 Deluxe Scroll Posterior Vitrectomy Pack.
3. CX9404 Bipolar Adaptor; CX9400, CX9420, CX9430 Bipolar Cords.
4. CX7000 Phaco Handpiece and CX7050 Frag Handpiece.
5. CX7100 Vertical Cut Microscissors and CX7150 Proportional Cut Microscissors Handpieces with Storz and ErgoTec® detachable tips.

Several existing Storz accessory devices will also be compatible with the Storz PREMIERE II System.

Predicate Devices: The Storz PREMIERE II Ophthalmic Microsurgical System and accessories are substantially equivalent to the following predicate devices:

The Storz PREMIERE II Microsurgical System is substantially equivalent to the Storz PREMIERE® Microsurgical System, the Alcon Series 20000® Legacy™ Microsurgical System, the SITE TXR™ System, and the Chiron CATALYST™ Microsurgical System;

The Storz CX7000 Phaco and CX7050 Frag Handpieces are substantially equivalent to the Storz DP8020 Phaco and DP7020 Frag Handpieces;

The Storz CX7100 and CX7150 Microscissors with detachable ErgoTec™ tips are substantially equivalent to the Grieshaber MPC and PSS Microscissors, and the Storz ErgoTec™ Vitreoretinal Instrument System;

The Storz CX4800 Deluxe Scroll Posterior Vitrectomy Pack and Storz CX4310 Deluxe Scroll Phaco Pack are substantially equivalent to the Storz DP4800 Posterior Vitrectomy Pack and the Storz DP4310 Deluxe Phaco Pack, respectively;

The Storz CX9404 Bipolar Coaxial Adaptor is substantially equivalent to the Storz DP9404 Bipolar Adaptor;

The Storz CX9430 and CX9400 Reusable Bipolar Cables are substantially equivalent to the Storz D8204 Reusable Bipolar Cable, and the Storz CX9420 Disposable Bipolar Cable to the Storz S2070 C Disposable Bipolar Cable.

Predicate Comparison: Charts comparing the PREMIERE II System and accessories listed above to their respective predicate devices, demonstrating substantial equivalence, are attached.

**Storz PREMIERE II Ophthalmic Microsurgical System
Substantial Equivalence Comparison - General Information**

Device Name / Manufacturer	Storz PREMIERE II Microsurgical Systems Storz Instrument Co.	Storz PREMIERE® Microsurgical System 510(k) K894278, K921460, K946227 Storz Instrument Co.	Alcon System 20000® Legacy™ Microsurgical System 510(k) K952213 Alcon Surgical, Inc.	SITE TXR™ System 510(k) K925828 SITE Microsurgical Systems, Inc.	Chiron CATALYST™ Microsurgical System 510(k) unknown Chiron Corp.
Intended Use	Anterior and Posterior Segment Ophthalmic Surgeries	Anterior and Posterior Segment Ophthalmics Surgeries	Anterior Segment Ophthalmic Surgery	Anterior and Posterior Segment Ophthalmic Surgeries	Anterior Segment Ophthalmic Surgery
Real-Time Display	Yes	Yes	Yes	Yes	Yes
Configurations Available	Anterior/Posterior/Both	Anterior/Posterior/Both	Anterior	Anterior/Both	Anterior
Modular Design	Yes	No	No	Yes	No
Programmable for Multiple Surgeons	Yes	Yes	Yes	Unknown	Yes
Remote Control	Yes	Yes	Yes	No	Yes
Multi-function Foot Control	Yes	Yes	Yes	Yes	Yes
Self-Diagnostics	Yes	Yes	Yes	No	Unknown
Error Processing	Yes	Yes	Yes	Yes	Unknown
On-Line Information	Yes	Yes	Yes	No	No
Disposable Accessories	Yes	Yes	Yes	Yes	Unknown
Automated IV Pole	Yes	Yes	Yes	No	Yes

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Electrical Power Requirements	100-120V 220-240V 50/60 Hz	100-120V 220-240V 50/60 Hz	100-120V 220-240V 47/63 Hz	Unknown	120V 240V 60 Hz
Operating Temperature	10°-40° C	10°-35° C	10°-35° C	10°-43° C	Unknown
Maximum Humidity	98% non-condensing	90% non-condensing	95% non-condensing	Unknown	44% non-condensing