



K 960009

MAR - 6 1996

510(k) Summary of Safety and Effectiveness

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

Submitted by:

Audrey Swearingen

Audrey G. Swearingen
Storz Instrument Company
3365 Tree Court Industrial Blvd.
St. Louis, MO 63122
314/225-5051

*Revised 510(k) Summary
9/5/96 / 2/16/96*

Contact Person: Audrey G. Swearingen
Regulatory Affairs Associate

Date Prepared: February 12, 1996

Proprietary Name: Storz S2050 series Bipolar Forceps

Common/Usual Name: Bipolar coagulation forceps

Classification Name: Electrosurgical Device, Cutting and Coagulation, and Accessories;
79(GEI)

Device Description: Storz S2050 series of bipolar forceps consists of twenty-one reusable devices for use with Storz DAISY™, Protegé®, and PREMIERE® Microsurgical Systems, and Storz S2080 Bipolar Coagulator. All forceps are of the same basic design with differences in tip configurations and handle dimensions. The patient contact portion of the S2050 series of forceps is composed of stainless steel. Some models have a nylon insulation on the handle region of the forceps.

Intended Use: The Storz S2050 series of bipolar forceps are used to control bleeding during surgical procedures, using high frequency electric current. Several of the forceps are designed for ophthalmic procedures specifically, while others are marketed for ENT procedures, neurosurgery, and/or plastic and reconstructive surgery. The forceps function by pinching tissue between the forcep tips, and allowing electric current to pass through it. The affected tissue is coagulated, and bleeding is arrested.

Predicate Devices: The Kirwan Bipolar Forceps (Kirwan Surgical Products, Inc.); and the Mentor O&O WET-FIELD Bipolar Forceps (Mentor O&O, Inc.).

Predicate Comparison: A table comparing the Storz S2050 series Bipolar Forceps to predicate devices, demonstrating substantial equivalence, is attached.

Storz S2050 Bipolar Forceps Substantial Equivalence Comparison

Manufacturer	Storz Instrument Company	Kirwan Surgical Products, Inc.	Mentor O & O, Inc.
Device	Storz Bipolar Forceps	Kirwan Bipolar Forceps	Mentor WET-FIELD™ Bipolar Forceps
Model(s)	S2050-XX series	Complete list of model numbers unknown	22-12XX series
Intended Use	Vessel coagulation during surgery	Vessel coagulation during surgery	Vessel coagulation during surgery
Patient-Contact Material Composition	410 and 17-7 Stainless steel	Stainless steel; material of "non-stick" models unknown	Unknown
System(s) for which Device is Designed	Storz DAISY®, Protégé®, and PREMIERE® Microsurgical Systems; and S2080 Bipolar Coagulator	No specific system known	Mentor WET-FIELD II™ Coagulator
Connector type	Two-pin male connector	Two-pin male connector	Two-pin male connector
Reusable/Single Use?	Reusable	Reusable	Reusable
Provided Sterile?	No	No	No