



JAN 31 1997

ENDOSCOPY 2590 Walsh Ave. Santa Clara, CA 95051

SUMMARY SAFETY AND EFFICACY

Device Name

Current Classification Name(s):

K 963765

Unipolar Endoscopic Coagulator-Cutter and Accessories, CFR 21 884.4160,
Class (II), Product code 85KNF

Electrosurgical Cutting and Coagulation Device and Accessories,
CFR 21 878.4400, Class (II), Product code 79GEI

Gynecologic Laparoscope and Accessories, CFR 21 884.1720, Class (II),
Product code 85HET

Common and Usual Name: Electrocautery Probe

Proprietary Name: Stryker StrykeFlow Electrocautery Probe

This summary of 510(k) safety and effectiveness is being submitted in accordance with requirements of SMDA 1990.

The Stryker StrykeFlow Electrocautery Probe is an electrosurgical device which enables the user to have the functions of electrocautery cutting and coagulation along with suction and irrigation in the same tool when used in combination with the Stryker Strykeflow Suction / Irrigator (K934094 and K954726). The Electrocautery Probe includes a variety of tip configurations for those laparoscopic surgical procedures where the delivery of electrosurgical current, irrigation, and suction via a single probe is desirable. The tips are packaged non-sterile for reusable purposes, and validated to packaging standard ASTM 4169.

The Electrocautery Probe is tested to a voluntary standard for electrosurgical devices, AAMI HF18.

The Electrocautery Probe is constructed of materials which are tested for biocompatibility per ISO-10993 and are safe, effective, and durable for their intended purposes. Sterilization is per AAMI SSSA and is validated for a minimum SAL of 10^{-6}

The Electrocautery Probe is equivalent in safety and effectiveness to a variety of devices currently marketed including the Valleylab Laparoscopic Handswitch/ Electrodes and the Stryker Strykeflow Suction / Irrigator Accessories. These devices are used in the applications noted above for general suction, irrigation, and electrocautery.

This device does not raise new issues when compared to its predicate devices or uses. Therefore, it is considered substantially equivalent to those devices.

Signature

Tom Keast
Design Engineer