



K963646

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ENDOSCOPY 2590 Walsh Ave. Santa Clara, CA 95051

SUMMARY SAFETY AND EFFICACY**Device Name****Current Classification Name(s):**

Vacuum-powered Body Fluid Suction Apparatus CFR 21 Class II 880.6740
Irrigation Device CFR 21 Class I 880.6960
Gynecologic Laparoscope and Accessories CFR 21 Class II 884.1720
Gastroenterology-urology Evacuator CFR 21 Class II 876.4370
Laparoscope General and Plastic Surgery CFR 21 Class II 878.4400
Cardiopulmonary Bypass Cardiotomy Return Sucker CFR 21 Class II 870.4430
Ear, Nose, and Throat Manual Surgical Instrument CFR 21 Class II 874.4420

Common and Usual Name: Suction Irrigator GF or SIGF**Proprietary Name:** Stryker Strykeflow Suction Irrigator Gravity Flow**Device Sponsor**

Stryker Endoscopy
2590 Walsh Ave.
Santa Clara, CA 95051

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

The Stryker Strykeflow Suction Irrigator Gravity Flow (SIGF) is an irrigation suction device which is provided sterile for single use disposable application. The SIGF accepts a variety of tips for laparoscopic and open general surgery, laparoscopic and open obstetric surgery, laparoscopic and open urologic surgery, endoscopic and open nasal surgery, open otolaryngologic surgery, and open plastic surgery. The SIGF is validated per AAMI HF18 for electrocautery application. The tips may be sterile packaged and disposable (single-use only) or non-sterile packaged for reusable purposes.

The SIGF is constructed of materials which are tested for biocompatibility per ISO 10993 and are safe, effective, and durable for their intended purposes. Gamma irradiation validation is per AAMI standard ST 32, method 1, section 5.2.3.1. The minimum dose for an SAL of 10^{-6} is 1.66 Mrads.

The SIGF is equivalent in safety and effectiveness to a variety of devices currently marketed (the Nezhat-Dorsey device, the Stryker Strykeflow Suction Irrigator, and equivalent gravity flow and bulb/syringe devices) which are used in the applications noted above for general suction or irrigation purposes. Additionally, the suction/irrigator tips may serve as a cannula to the laparoscopic surgeon to provide a portal to the operation site similar to the function of the trocar cannula.

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

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