

K963642

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stryker[®]

ENDOSCOPY 2590 Walsh Ave. Santa Clara, CA 95051

SUMMARY SAFETY AND EFFICACY

Device Name

Current Classification Name:

Vacuum-powered Body Fluid Suction Apparatus CFR 21 Class II 880.6740
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
Arthroscopic Accessories CFR 21 Class II 888.1100
Cardiopulmonary Bypass Intracardiac Suction Control CFR 21 Class II 870.4430

Common and Usual Name: Suction Regulator or SSR
Proprietary Name: Stryker Suction Regulator

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 Suction Regulator (SSR) controls the rate of suction from any product that requires suction control. It consists of an inlet tube with a suction adapter at the end, an outlet tube with a suction adapter at the end, and a handpiece. The handpiece controls suction by varying the amount of ambient air entering the tube set. As more air is let into the tube set, suction force at the inlet tube is reduced. As less air is let into the tube set, suction force is increased.

The SSR is constructed of materials which are tested for biocompatibility per ISO 10993 and are safe, effective, and durable for their intended purposes. The SIGF ETO sterilization processes are validated per AAMI standard ST 27, to a SAL of 10^{-6} . 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 SSR is equivalent in safety and effectiveness to the Arthrex Suction Regulator. It is intended for uses in any procedure in which the control of suction force is desired.

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



Tony Lee
Senior Design Engineer