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**Hydro-Surg® Laparoscopic Irrigator**

**Section VII.**

**510(k) Summary of Safety and Effectiveness Information**

**A. Submitter Information**

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**B. Device Name**

Trade Name:	<b>Hydro-Surg</b> Laparoscopic Irrigator
Common/Usual Name:	Laparoscopic Irrigator
Classification Name:	Endoscope and Accessories Gynecologic Laparoscope and Accessories

**C. Predicate Device Names**

Trade Name:	Endo-Flo Irrigation System (Davol Inc.)
Trade Name:	StrykeFlow Disposable Suction Irrigator (Stryker Endoscopy)

**D. Device Description**

The **Hydro-Surg** Irrigator uses a mechanical pumping system to generate fluid output. It is powered with four (4) standard AA alkaline batteries with an output amperage of approximately 1.0 amperes, with a voltage of 6 volts, direct current (dc). The batteries power a motor which activates movement of an impeller pump which drives the irrigation fluid to a preattached trumpet valve irrigation probe for delivery to the operative site.

The proposed **Hydro-Surg** Irrigator system is designed for single patient use and allows for activation up to approximately 10 minutes. The flow rate of fluid delivered by the system is controlled by the surgeon with minimum flow rates of approximately 1200 cc/minute dependent on the surgeon's tip selection.

Following completion of the procedure, the batteries, which power the **Hydro-Surg** Irrigator, may be removed for proper disposal by pushing in the tabs located on each side of the battery casing and pulling the battery casing apart.

E. Intended Use of the Device

The **Hydro-Surg** Irrigator is designed to be used in conjunction with a laparoscopic probe handle and tip to provide controlled powered irrigation/aspiration during laparoscopic surgical procedures (e.g., laparoscopic cholecystectomy and laparoscopic gynecological procedures). It may also be used for resection of filmy adhesions (i.e., hydrodissection) and peritoneal lavage.

F. Summary of Similarities and Differences

The 510(k) Substantial Equivalence Decision-Making Process (Detailed) decision tree (ODE guidance memo #K86-3) was utilized to make a determination of substantial equivalence (see Exhibit VII-I). The answers to the following questions from this decision tree lead to a determination of substantial equivalence.

1. **Does New Device Have Same Indication Statements?**

**Yes.** The proposed **Hydro-Surg** Irrigator and the Predicate Endo-Flo are designed to be used in conjunction with a laparoscopic probe handle and tip to provide controlled powered irrigation/aspiration during laparoscopic surgical procedures (e.g., laparoscopic cholecystectomy and laparoscopic gynecological procedures). It may also be used for resection of filmy adhesions (i.e., hydrodissection) and peritoneal lavage.

The unit label of the Predicate StrykeFlow does not specifically set out its intended use. However, from its description, the intended use of the Predicate StrykeFlow appears to be identical to the proposed **Hydro-Surg** Irrigator.

2. **Does New Device Have the Same Technological Characteristics, e.g., Design, Materials, etc.?**

No. Though the three systems have the same basic components (i.e., power source, pump, irrigation/suction tubing set), the design of these components may vary. However, all three pumps have been designed to be completely disposable and are for single patient use only.

The currently marketed Predicate Endo-Flo has a diaphragm pump powered by a compressed gas source (pneumatic pump) and is a positive displacement type pump. Therefore, its technological characteristics differ from the battery-powered systems. Both the **Hydro-Surg** Irrigator and the Predicate StrykeFlow are battery-powered devices which utilize an impeller pump for fluid output. However, the materials of manufacture may be different and some of the internal pumping components may differ. Examples of differences between the two devices include that the Predicate StrykeFlow is powered by eight (8) AA alkaline batteries; whereas, the **Hydro-Surg** Irrigator utilizes four (4). The batteries in the **Hydro-Surg** Irrigator can be removed for proper disposal by the user; but the batteries in the Predicate StrykeFlow cannot be removed from its casing. Additionally, the **Hydro-Surg** Irrigator contains a smaller motor than the Predicate StrykeFlow.

**3. Could the New Characteristics Affect Safety or Effectiveness?**

**Yes.** The differences between the proposed **Hydro-Surg** compared to the Predicate Endo-Flo and Predicate StrykeFlow could affect both safety and effectiveness.

**4. Do the New Characteristics raise New Types of Safety or Effectiveness Questions?**

**No.** Irrigators, such as the proposed **Hydro-Surg** Irrigator, are generally intended to provide controlled powered irrigation during laparoscopic surgical procedures. The safety and effectiveness questions are not new and include questions concerning fluid flow rates deliverable and product longevity.

**5. Do Accepted Scientific Methods Exist for Assessing Effects of the New Characteristics?**

**Yes.** The assessment of the effects of the characteristics of the proposed **Hydro-Surg** Irrigator can be determined using relatively simple experimental methods for determination of fluid output and product longevity. Industry standards exist for the biological evaluation of the product's fluid contacting materials to assure that materials are suitable for their intended use.

**6. Are Performance Data Available to Assess Effects of New Characteristics?**

**Yes.** Laboratory bench testing was performed to assess the effects of the new characteristics of the proposed **Hydro-Surg** Irrigator. These tests compared the proposed **Hydro-Surg** Irrigator against the Predicate Endo-Flo and Predicate

StrykeFlow. The objective of the laboratory testing was to determine substantial equivalence of the performance characteristics between the **HYDRO-SURG** Laparoscopic Irrigator and the predicate devices, Endo-Flo Irrigator and Stryker StrykeFlow. Specific performance characteristics evaluated included assessment of fluid flow rates (all three irrigators evaluated) and product longevity (battery-powered units only).

In addition, biocompatibility testing, performed in accordance with ODE memorandum #G95-1 (International Standard ISO-10993, Part 1), has been performed on the fluid contacting materials used to manufacture the proposed **Hydro-Surg** Irrigator.

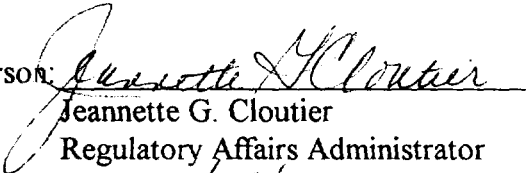
**7. Does Performance Data Demonstrate Equivalence?**

**Yes.** The test data demonstrate that the performance of the **HYDRO-SURG** Laparoscopic Irrigator in terms of flow rate capability and product longevity is suitable for its intended use, and the device is substantially equivalent to the predicate Endo-Flo and StrykeFlow irrigators. Furthermore, results from biocompatibility testing performed from this testing have demonstrated that the materials are suitable for their intended use as a tissue/bone/dentin externally communicating device of limited duration.

**Conclusion:**

Based on the FDA's decision tree, the subject device, the **Hydro-Surg** Laparoscopic Irrigator, is substantially equivalent to the predicate devices, Endo-Flo and StrykeFlow irrigators.

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