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510(k) Summary of Safety and Effectiveness Information for the Davol HydroFlex LI System

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

1) **Submitter Information:**

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2) **Device Name:**

Trade Name: HydroFlex LI Laparoscopic Irrigation System
Common/Usual Name: Laparoscopic Irrigator
Classification Name: Laparoscope, General & Plastic Surgery

3) **Predicate Device:**

- Davol Endo-Flo System (K902722)
- U.S. Endoscopy Group's Laparoscopic Irrigation System and Laparoscopic Irrigation Tubing Set (K911493 and K911484)
- Linvatec Apex™ Universal Irrigation System (K933873)

The HydroFlex LI system proposed in this submission is substantially equivalent to Davol's currently marketed Endo-Flo system (K902722), the U.S. Endoscopy Group's Laparoscopic Irrigation System and Laparoscopic Irrigation Tubing Set (K911493 and K911484), and the Linvatec Apex™ Universal Irrigation System (K933873). All four devices are designed to provide controlled irrigation to the operative site during laparoscopic procedures. For purposes of this submission, the Davol Endo-Flo is the primary predicate device. The U.S. Endoscopy Group's Laparoscopic Irrigation System and Suction Irrigation Tubing Set and the Linvatec Apex™ Universal Irrigation System are provided for comparison specifically because they are driven by an electro-mechanical pump as is the HydroFlex LI system. In addition, the Linvatec Apex™ Universal Irrigation System is also provided as a comparison because it represents a multi-purpose fluid delivery system.

4) **Description and Intended Use of the Device:**

The HydroFlex LI System is designed to provide controlled irrigation during laparoscopic procedures. The system helps flush blood and tissue debris from the operative site during laparoscopy to aid in visualization. It may also be used for dissection of filmy adhesions (i.e. hydrodissection), hydrodissolution of blood clot formations, and peritoneal lavage.

The HydroFlex LI disposable Pumping Chamber/Tubing Set is intended for use with the HydroFlex irrigation pump Controller. Pressure in the pumping chamber is determined by the setting on the main Controller which is calibrated to account for two feet of bag height above the outflow. Maximum static pressure (all outflow closed and no fluid flow) applied to the pre-attached probe tip is limited to approximately 500 mmHg, or 10.0 psig, by the main controller. The controller defaults to gravity at an input pressure less than 70mmHg. Rate of flow is dependent upon pressure selection on the controller and probe tip selection.

Fluid will not flow when the back pressure in the system equals the pressure setting on the controller, e.g., when the probe is in the off position. Under static pressure conditions with no outflow, this will equal the controller setting. The impeller continues to spin even with flow stopped, and, in this way, the selected pressure is maintained. Flow will automatically resume when system back pressure falls below the selected pressure, e.g., when the probe is open to flow.

5) **Summary of Similarities and Differences in Technological Characteristics, Performance and Intended use:**

A comparison chart is provided which summarizes the similarities and differences in intended use, technological characteristics and performance between the four systems (ref. Attachment 1 of this section).

The 510(k) "Substantial Equivalence Decision Making Process (Detailed)" decision tree (ref. Attachment 2 of this section) was utilized to make a determination of substantial equivalence. The answers to the decision tree questions lead to a determination of substantial equivalence.

1. Does the New Device Have the Same Indication Statement?

Yes. The Davol HydroFlex LI system and the Davol Endo-Flo are intended to provide controlled irrigation during laparoscopic procedures. The devices flush blood and tissue debris from the operative site during laparoscopy to aid in visualization and may also be used for

dissection of filmy adhesions (i.e. hydrodissection), hydrodissolution of blood clot formations, and peritoneal lavage.

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

No. Although the HydroFlex LI system and Endo-Flo have the same basic components (pump, irrigation tubing, inflow connectors) the design of these components may vary as well as the principle of operation.

The currently marketed Endo-Flo pump has a diaphragm pump powered by a compressed gas source (pneumatic pump). The input gas pressure is determined by the users adjustment of the pressure regulator at the nitrogen/air source. The vibration of the diaphragm drives the flow of irrigant from the system.

The HydroFlex LI system is driven by an impeller pump which is powered by an electronic Controller (electro-mechanical control is similar to U.S. Endoscopy Group's Laparoscopic Irrigation System and Suction Irrigation Tubing Set and the Linvatec Apex™ Universal Irrigation System). The input pressure is determined by the user selected setting on the electronic Controller. The Controller determines the speed of the impeller pump which drives the flow of irrigant.

In addition, the design of the HydroFlex system reusable main Controller is such that it can be used as a multi-purpose fluid irrigation system (dependent on the disposable Pump Tubing set used with the Controller).

Both systems contain fluid contact components made from cyrolite and polyvinylchloride. Other materials of the HydroFlex LI system differ from the Endo-Flo system.

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

Yes. The change in pump mechanism and power source could affect the effectiveness of the irrigation device's ability to provide an adequate irrigant flow rate for laparoscopic procedures. The principle of operation of the HydroFlex LI system (electronic) could affect the safety of the system in regards to electrical issues.

The ability to use the reusable Controller for multiple types of procedures (i.e. laparoscopic and arthroscopic) could affect the safe and effective use of the product if the user were to misuse the product and use the incorrect disposable with the reusable Controller. The Linvatec Apex™ Universal Irrigation System has this identical

feature (multi-use indication).

The use of different fluid contact materials in the HydroFlex LI system could affect the safe and effective use of the system if the materials were not biocompatible.

The response to questions 5 and 6 below address the assessment of the affects of the new characteristics on safety or effectiveness.

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

No. The question regarding the ability of a laparoscopic irrigation system to provide an adequate flow of irrigant during laparoscopic procedures is the same for the HydroFlex LI system and the Endo-Flo.

The question of electrical safety is not new as there are other electro-mechanical laparoscopic irrigation systems available (U.S. Endoscopy Group's Laparoscopic Irrigation System and Suction Irrigation Tubing Set and the Linvatec Apex™ Universal Irrigation System).

The question of product misuse due to the ability of the Controller to be utilized for multiple procedures is not new. The Linvatec Apex™ Universal Irrigation System is a multi-purpose fluid delivery system which is utilized for both arthroscopic and laparoscopic procedures.

Note: The Davol HydroFlex LI disposable Pump Chamber/Tubing set will be labeled with the following Contraindication "Not for use in Hysteroscopy or Cavity Distention" and will be provided with a pre-attached laparoscopic suction/irrigation probe.

The question of material biocompatibility is not a new type of safety or effectiveness question as the predicate device materials must also be compatible.

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

Yes. The assessment of the characteristics of a laparoscopic irrigation system (adequate flow rates) can be performed by utilizing relatively simple experimental methods. Well accepted tests are available for assessing the biocompatibility of new materials for use in medical devices. Electrical safety standards are available for devices such as the HydroFlex LI system (UL 2601-1, ANSI/AAMI ES1-1993: Safe Current Limits for Electromechanical Apparatus).

ATTACHMENT I

Reusable Pump has Multiple Indications:	Yes	NA	No	Yes