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510(k) Summary of Safety and Effectiveness Information for the Davol Hydro-Flex HD System

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

DEC 11 1997

1) **Submitter Information:**

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Date Of Preparation: December 10, 1996

2) **Device Name:**

Trade Name: HydroFlex HD Hysteroscopic Distention and Irrigation System
Common/Usual Name: Hysteroscopic Distention System
Classification Name: Hysteroscopic Insufflator, Obstetrics & Gynecology

3) **Predicate Device:**

- Zimmer CDIS System (K901068)
- Linvatec Apex™ Universal Irrigation System (K933873)

The HydroFlex HD system proposed in this submission is substantially equivalent to the Zimmer CDIS™ Controlled Distention Irrigation System (K901068, and the Linvatec Apex™ Universal Irrigation System (K933873). All three devices are designed to provide distention and irrigatin of the uterus with low viscosity fluids during diagnostic or operative hysteroscopy. A comparison chart is provided which summarizes the similarities and differences in intended use, design and performance between the three systems (ref. Attachment 1 of this section). For purposes of this submission, the Zimmer CDIS™ Controlled Distention Irrigation System is the primary predicate device. The Linvatec Apex™ Universal Irrigation System is provided for comparison specifically because it represents a multi-purpose fluid delivery system.

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

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The HydroFlex HD system is designed to provide distention and irrigation of the uterus with low viscosity fluids during diagnostic or operative hysteroscopy. The system distends the uterus for for better visualization during hysteroscopic procedures and flushes blood and tissue debris from the operative site.

The HydroFlex HD hysteroscopic distention 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 16 inches of bag height above the outflow. Maximum static pressure (all outflow closed and no fluid flow) applied to the intrauterine space is limited to approximately 100mmHg or 2.0 psig, by the main controller. Rate of flow is dependent upon the pumping chamber pressure.

Fluid will stop flowing when the back pressure in the system equals the pressure setting on the controller. Under static pressure conditions with no outflow this will equal the intrauterine pressure. 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.

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 three systems (ref. Attachment 1 of this section).

The 510(k) "Substantial Equivalence Decision Making Process (Detailed)" decision tree 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 HD system and the Zimmer CDIS Controlled Distention Irrigation System are intended to provide distention and irrigation of the uterus with low viscosity fluids during diagnostic or operative hysteroscopy. The devices distend the uterus for better visualization during hysteroscopic procedures and flush blood and tissue debris from the operative site.

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

   No. Although the HydroFlex HD system and Zimmer CDIS Controlled Distention Irrigation system have the same basic components (pump, irrigation tubing, inflow

connectors) and the design of both pumps is electro-mechanical, the principle of operation of the disposable tubing sets and other design features vary.

The Zimmer CDIS Controlled Distention Irrigation System pump functions by means of a mechanical piston pump powered by an electronic reusable pump console. The piston pump cassette is placed into the chamber of the pump console and the piston drive forces fluid through the tubing set into the hysteroscope and subsequently the uterine cavity at a pre-determined pressure setting selected by the user. The Zimmer CDIS system also contains a monitor tube which connects to the hysteroscope and to a pressure sensor in the pump console. This allows for measurement of the fluid pressure for distention of the uterine cavity.

The HydroFlex HD system is driven by an impeller pump which is powered by an electronic Controller. 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 and determines the resultant static pressure. Both the HydroFlex HD and the Zimmer CDIS system contain a pressure relief valve which limits the maximum intrauterine static pressure by releasing fluid through the valve and drain tube. The HydroFlex HD system pressure relief valve relieves static pressures if the pressure reaches 150mmHg. The Zimmer CDIS system pressure relief valve limits static pressures if the pressure reaches the range of 100-110mmHg.

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). This 510(k) submission covers the hysteroscopic distention and irrigation indication for use.

Both systems are used only with low viscosity fluids for distention and irrigation of the uterine cavity.

3. Could the New Characteristics Affect Safety or Effectiveness?

Yes. The difference in the pump mechanism (impeller versus piston) could affect the effectiveness of the irrigation device's ability to provide an adequate irrigant flow rate and pressure for hysteroscopic distention. Since the principle of operation of both reusable pumps is the same (electronic) there are no new safety issues in regards to electrical issues.

The difference in the maximum selectable pressures for the two systems (100mmHg for HydroFlex HD verses 85mmHg for Zimmer CDIS) could affect the effectiveness of the systems in providing adequate irrigation and distention.

The ability to use the reusable Controller for multiple types of procedures (i.e.

hysteroscopic, 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 use of different fluid contact materials in the two systems could affect the safe and effective use of the system if the materials were not biocompatible.

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

No. The question regarding the ability of a hysteroscopic distention and irrigation system to provide an adequate flow of irrigant for distention during hysteroscopic procedures is the same for the HydroFlex HD system and the Zimmer CDIS system.

The difference in the maximum selectable pressure is not a new type of safety or effectiveness issue as it relates to hysteroscopic distention and irrigation devices. This question of the safe and effective pressure to use during a hysteroscopic procedure for distention and irrigation pertains to all hysteroscopic distention pump systems.

The question of electrical safety is not new as they are both electro-mechanical systems.

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

The question of product misuse due to the ability of the HydroFlex 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 hysteroscopic, arthroscopic and laparoscopic procedures. The following design features have been established in order to minimize the chance of the HydroFlex being used inadvertently for the incorrect procedure:

1) The Davol HydroFlex LI laparoscopic disposable Pump Chamber/Tubing set is labeled with the following Contraindication "Not for Hysteroscopy or Cavity Distention". It will also be provided with a pre-attached laparoscopic suction/irrigation probe which is not used during hysteroscopic or arthroscopic procedures. The Davol HydroFlex AD arthroscopic disposable Pump Chamber/Tubing set is labeled with the following contraindication "Not for Hysteroscopy". The Davol HydroFlex HD hysteroscopic disposable Pump Chamber/Tubing set will be labeled with "HydroFlex Tubing Set HYSTEROSCOPY").

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2) The LED on the front panel of the Controller displays the correct procedure for the disposable which has been loaded (i.e. LAP. ARTH or HYST). This is accomplished by the presence of recognition switches on the underside of the Controller which mate with recognition "bumps" on the lid of the disposables. Each of the three disposables have a unique placement of these "bumps" which depress the appropriate recognition switches. After the LED displays the procedure, the user must then depress the "CONFIRM PROCEDURE" button to confirm that the procedure displayed is the appropriate for the intended surgical procedure.

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 hysteroscopic distention and irrigation system (adequate static intra-uterine pressures and irrigation 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 HD system (UL 2601-1, ANSI/AAMI ES1-1993: Safe Current Limits for Electromechanical Apparatus) as well as electromagnetic compatibility standards (IEC 601-1-2).

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

Yes. Laboratory bench testing has been performed to assess the effects of the new characteristics of the HydroFlex HD system as compared to the Zimmer CDIS System. This testing included the measurement of static pressure and flow rates from both systems when used without attachment to a hysteroscope and when attached to three different hysteroscopes at low, mid-range and maximum input pressures.

Testing was also performed on the HydoFlex HD Pressure Relief Valve to document the pressure at which the valve relieves fluid pressure.

Biocompatibility testing, performed in accordance with the FDA General Program Memorandum #G95-1, has been conducted on all materials utilized in the fluid path of the HydroFlex HD system.

The HydroFlex HD system will conform to the applicable safety electrical standards (UL 2601-1 and ANSI/AAMI ES1-1993: Safe Current Limits for

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Electromechanical Apparatus) as well as applicable electromagnetic compatibility standards (IEC 601-1-2).

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

Yes. Based upon the results of the laboratory testing the HydroFlex HD system is substantially equivalent to the Zimmer CDIS system in regards to the devices ability to provide an adequate flow rate and pressure for the distention and irrigation of the uterine cavity during hysteroscopy. The results of the Pressure Relief Valve (PRV) testing demonstrate the ability of the HydroFlex PRV to relieve pressures to an acceptable level for hysteroscopic distention procedures. Results from the biocompatibility testing have shown that the materials to be used for the manufacture of the disposable HydroFlex HD system are suitable for externally communicating devices with limited duration tissue contact.

CONCLUSION:

Based upon the above information, the Davol HydroFlex HD system is substantially equivalent to the Zimmer CDIS system, and the Linvatec Apex Universal Irrigation System.

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Manager of Regulatory and Clinical Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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DEC 11 1997

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Re: K970078
HydroFlex HD Hysteroscopic Distention System
Dated: October 31, 1997
Received: November 13, 1997
Regulatory Class: II
21 CFR §884.1700/Product Code: 85 HIG

Dear Ms. Drago:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number: [redacted] K970078

Device Name: **DAVOL HYDROFLEX HD HYSTEROSCOPIC DISTENTION SYSTEM**

Indications for Use: **The HydroFlex HD Hysteroscopic Distention System is intended to provide distention and irrigation of the uterus with low viscosity fluids during diagnostic or operative hysteroscopy.**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P Rathbun
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K970078

Prescription Use ✓ **Or** **Over-The-Counter Use**____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)