2/19/99

K982867

510(k) Summary of Safety and Effectiveness Information for the modified Davol HydroFlex™ HD System

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

1) **Submitter Information:**

Submitter's Name: Robin M. Drago
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Cranston, RI 02920
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Contact Person: Robin M. Drago
Date Of Preparation: February 15, 1999

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:**

- HydroFlex™ HD Hysteroscopic Distention System (970078)
- Karl Storz Hamou Endomat® (K936231)

The modified HydroFlex HD system described in this submission is substantially equivalent to the original HydroFlex HD system (K970078) and the Karl Storz Hamou Endomat (K936231). All of these devices are designed to provide distention and irrigation of the uterus with low viscosity fluids for diagnostic and/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).

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

The modified 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 better visualization during hysteroscopic procedures and flushes blood and tissue debris from the operative site.

The modified 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 modified Davol HydroFlex HD system, the original HydroFlex HD system, and the Karl Storz Hamou Endomat are intended to provide distention and irrigation of the uterus with low viscosity fluids for diagnostic and/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.?**

   Yes. The modified HydroFlex HD system and the original HydroFlex HD system have the same technological characteristics and fundamental scientific technology. The modified HydroFlex HD system (as well as the original 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 modified HydroFlex HD and the original HydroFlex HD system contain a Pressure Relief Valve (PRV) which limits the maximum intrauterine static pressure by releasing fluid through the valve and drain tube. The modified and original HydroFlex HD systems PRV relieves static pressures to below 150mmHg.

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) as was described in the original HydroFlex HD system 510(k). There have been no modifications to the reusable Controller to allow for it's use with the modified HydroFlex HD system.

There are some minor material differences but all materials are biocompatible. Both systems are used only with low viscosity fluids for distention and irrigation of the uterine cavity.

3. Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

No. Although the modified HydroFlex HD system and the original HydroFlex HD system have the same intended use and technological characteristics there has been a change to increase the flow rate of the modified HydroFlex HD system. The increased flow rate allows for better distention and visualization of the uterus when higher levels of outflow are being utilized with the hysteroscope outflow port. In this manner, distention is maintained under higher levels of outflow while the maximum static pressure reached within the uterus is the same as with the original HydroFlex HD system.

The change made to increase the flow rate of the modified HydroFlex HD raises a question regarding the ability of the system to meet the higher flow requirement and to continue to maintain static intrauterine pressures at the same levels as the original HydroFlex HD system.

In order to highlight the importance of fluid monitoring a new Warning has been added to the Instructions For Use provided with the modified HydroFlex HD system. This Warning states the following:

"**Warning**: the HydroFlex HD Hysteroscopic Distention System is a high flow system capable of delivering up to 600 ml/min., depending on the size of the sheath and scope. Under high flow conditions, fluid absorption and its consequent problems can be accelerated. It is important to carefully monitor the fluid-in/fluid-out difference,

and you may wish to consider use of an automated monitoring system, such as the AquaSens™ Fluid Monitoring System (Davol product code #0025333)."

Material changes made also required additional testing be performed to assure the new materials were biocompatible.

4. Are Performance Data Available to Assess Equivalence?

Yes. Testing was performed to evaluate the effect of the modifications on performance of the modified HydroFlex HD as compared to the data obtained for the original HydroFlex HD system. This testing included:

1) measurement of maximum static pressure for each of the three devices to ensure equivalence

2) irrigation flow rates obtainable out the distal end of the device with and without hysteroscopes attached were measured to ensure equivalence

3) fluid relief pressure testing of the Pressure Relief Valve (PRV) was measured to document the pressure at which the valve relieves to ensure equivalence to the original HydroFlex HD PRV

In addition, testing was performed on the modified HydroFlex HD system to assess the effects on pressure and flow rate of raising or lowering the fluid irrigation bags beyond the recommend height of 16". Testing was also performed to document the ability of the modified HydroFlex HD system to continue functioning with out loss of performance when the PRV is dripping and not releasing fluid in a steady stream mode.

Testing which was performed on the Hamou Endomat system (K936231), and had been provided in the original HydroFlex HD 510(k) (K970078), is provided for comparison purposes in Exhibit VIII of this submission.

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 modified HydroFlex HD system.

The HydroFlex Controller conforms to the applicable safety electrical standards (UL 2601-1 and ANSI/AAMI ES1-1993: Safe Current Limits for Electromechanical Apparatus) as well as applicable electromagnetic compatibility standards (IEC 601-1-2). Test results were provided in the original HydroFlex HD 510(k) submission (K970078). Since no changes have been made to the HydroFlex Controller this data continues to be applicable.

5. Performance Data Demonstrate Equivalence?

Yes. The results of the testing performed demonstrates that the Static Pressure of the modified HydroFlex HD system is substantially equivalent to the original HydroFlex HD system. Both systems tested are below the maximum static pressure of 150mmHg which is described as the maximum pressure which should not be exceeded in the August 1, 1995 "Draft Submission Guidance for a 510(k), Hysteroscopic and Laparoscopic Insufflators".

The results of the flow rate testing demonstrate that the modified HydroFlex HD system is able to provided a higher flow rate than the original HydroFlex HD system and also provides a substantially equivalent flow rate as compared to the Hamou Endomat system.

The results of the Pressure Relief Valve (PRV) testing demonstrates the ability of the modified HydroFlex PRV to relieve pressures to an acceptable level for hysteroscopic distention procedures and is equivalent to the original HydroFlex HD system PRV.

Results from the biocompatibility testing have shown that the materials to be used for the manufacture of the modified HydroFlex HD system are suitable for externally communicating devices with limited duration tissue contact.

CONCLUSION:

Based upon the above information, the modified Davol HydroFlex HD system is substantially equivalent to the original HydroFlex HD system and the Karl Storz Hamou Endomat system. Data generated from the testing of the devices demonstrates substantial equivalence.

Robin M. Drago
Manager of Regulatory and Clinical Affairs

ATTACHMENT 1
COMPARISON CHART

Feature	Modified HydroFlex HD (Current Submission)	Original HydroFlex HD (K970078)	Karl Storz Hamou Endomat® (K936231)
Intended Use:	The intended use of the above irrigation systems is to provide distention and irrigation of the uterus with low viscosity fluids for diagnostic and/or operative hysteroscopy.		
Other Applications:	Laparoscopic Irrigation Arthroscopic Irrigation	Laparoscopic Irrigation Arthroscopic Irrigation	Laparoscopic Irrigation
Pump Design:	Electro-mechanical	Electro-mechanical	Electro-mechanical
Pump Mechanism:	Impeller	Impeller	Roller
Max. Instillation Pressure:	Hysteroscopic 100mmHg Laparoscopic 500mmHg Arthroscopic 300mmHg	Hysteroscopic 100mmHg Laparoscopic 500mmHg Arthroscopic 300mmHg	Hysteroscopic 200mmHg Laparoscopic 400mmHg
Pressure Relief Valve Setting:	150mmHg	150mmHg	None
Average Max. Flow Rate:	608ml/minute	393ml/minute	600ml/minute
Tested Max. Flow Rate:	630ml/minute	410ml/minute	600ml/minute

Feature	Proposed HydroFlex HD (Current Submission)	Original HydroFlex HD (K970078)	Karl Storz Hamou Endomat® (K936231)
Pressure Control:	Pressure selected at electronic Controller	Pressure selected at electronic Controller	Pressure selected at electronic Controller
Disposable Supplied Sterile:	Yes	Yes	Yes
Pressure Monitor:	No	No	Yes
Flow Monitor:	No	No	Yes
Volume Monitor:	No	No	No
Alarm:	No	No	Yes
Reusable Pump:	Yes	Yes	Yes
Reusable Pump Supplied Non-Sterile:	Yes	Yes	Yes
Reusable Pump has Multiple Indications:	Yes	Yes	Yes

Feature	Proposed HydroFlex HD (Current Submission)	Original HydroFlex HD (K970078)	Karl Storz Hamou Endomat® (K936231)
Display Parameters:	*Set/Maximum Potential Static Pressure *Procedure (at beginning of procedure)	*Set/Maximum Potential Static Pressure *Procedure (at beginning of procedure)	*Set/Actual Pressure *Flow Rate *Suction Pressure

NOTE: The Hamou Endomat (K936231) is provided in this submission as an example of a 510(k) concurred multi-application pump which also provides flow rates of 600 ml/minute. Testing was performed and provided in the original HydroFlex HD 510(k) (K970078) which demonstrates a maximum flow rate of 600 ml/min. Exhibit VIII of this submission contains the summary data from this testing. Maximum Pressure settings are within the criteria set within the "Hysteroscopic and Laparoscopic Insufflators: Submission Guidance for a 510(k)"Draft: August 1, 1995.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 1999

Ms. Robin M. Drago
Manager of Regulatory and Clinical Affairs
Davol, Inc.
Subsidiary of C.R. Bard, Inc.
100 Sockanossett Crossroad
Cranston, RI 02920

Re: K982867
Hydroflex HD Hysteroscopic Distention System - Modified
Dated: December 15, 1998
Received: December 16, 1998
Regulatory Class: II
21 CFR 884.1700/Procode: 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 legally marketed predicate 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section I - D

510(K) Number: K982867

Device Name: PROPOSED DAVOL HD HYSTEROSCOPIC DISTENTION SYSTEM

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982867/S001

(Optional Format 1-2-96)