SEP 13 1999

K991799

6.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION:

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:	Lucinda L. Fox
Address:	Davol Inc. 100 Sockanossett Crossroad Cranston, Rhode Island 02920
Phone Number:	(401) 463-7000
Fax Number:	(401) 463-3845
Contact Person:	Lucinda L. Fox
Date of preparation:	May 25, 1999

2) Device Name:

Trade Name:	Davol® Hysteroscopy Pouch Drape and Tubing Set
Common/Usual Name:	Surgical Drape/Suction Tubing
Classification Name:	Suction Tube 80 GCX Exempt Drape 79 KKX General & Plastic Surgery

3) Predicate Product:

Microtek Medical, Inc. Under Buttocks Drape and Fluid Collection Pouch Preamendment

4) Description and Intended Use:

4.1 Intended Use:

The Davol® Hysteroscopy Pouch Drape and Tubing Set is intended for the collection of distention and irrigation fluids during diagnostic or operative hysteroscopy.

4.2 Device Description:

The **Davol** Hysteroscopy Pouch Drape and Tubing Set consists of a Drape and Fluid Collection Tubing.

The Drape is a blue polyethylene under-buttocks sheet with a clear, funnel-shaped polyethylene fluid collection pouch. The sheet has a patient adhesive strip located at the edge closest to the pouch, as well as hand cuffs to facilitate placement under the patient. The cuffs are identified as *left* and *right.* The pouch is held open by a malleable wire support located at the top outside edge and it contains a spunbonded nylon fabric filtration screen to catch large tissue debris or surgical gauze, which prevents clogging the drainage port. The drainage port, located at the bottom of the pouch, has a hinged cap.

The Fluid Collection Tubing includes a Drape Suction Set and an Outflow Tubing Set. The Drape Suction Set is supplied in a Y-configuration manufactured from three pieces of polyvinylchloride (PVC) tubing joined by a PVC Y-Connector. The Ouflow Tubing Set includes an anti-siphon feature which allows air to vent into the fluid path of the outflow tubing. When air cannot vent into the outflow fluid path, intrauterine distention pressure may be decreased or "offset" due to a siphoning action when the outflow tube is oriented vertically. This action, caused by gravity or suction, is due to the different pressure between the top (intrauterine cavity) and the bottom of the outflow tube. The difference in pressure tends to offset or siphon down the pressure at the top of the outflow tubing, thereby potentially decreasing the intrauterine distention. When the flow rate increases, the intrauterine pressure produced by a distention system may be lowered due to the above described offset in pressure; e.g. the siphoning effect.

The anti-siphon feature of the Outflow Tubing Set merely provides a means for air to vent into the fluid path of the outflow tubing, which breaks the siphoning effect. The anti-siphon connector contains raised ribs so that an air vent is created when the outflow tubing is bonded to the connector. A PVC outer sheath has been added to capture fluid that may leak out of the air vent in the event the outflow tubing is filled and positioned horizontally. The outer sheath serves no other function except to capture potential fluid leakage through the air vent and carry it further down the outflow tubing for discharge into the Pouch or into the Drape Outflow Tube. Use of the Outflow Tubing Set with its anti-siponing feature allows fluid outflow to be captured without compromising intrauterine distention.

4.3. Device Use:

The Drape is placed under the patient's buttocks and secured to the patient using the adhesive strip located at the bottom edge just above the fluid collection pouch. The pouch is draped off the end of the O.R. table, which is held open by a malleable wire support located at the top outside edge. The Drape Suction Set is connected to the drainage port at the bottom of the pouch and to a suction source. The Outflow Tubing Set is connected to the scope's outflow port and drape inside the fluid collection pouch for gravity drainage. If the user wishes to connect the Outflow Tubing Set to the Drape Suction Set for suction assist, it may be connected to the short leg of the Drape Suction Set. The distention pressure of hysteroscopic distention pumps will vary. If using suction outflow, the user should adjust the suction level according to the desired outflow rate.

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

The Fluid Collection Tubing Set, as a "vacuum powered body fluid suction apparatus" under 21 CFR §878.6740, was exempted from the premarket notification requirement (published in Federal Register Vol. 63, No. 13, Wednesday, January 21, 1998). In light of this exemption, Davol is limiting its substantial equivalence claim for the Drape/Tubing Set to the Drape portion of the proposed product.

The Drape described in this submission is identical to the product supplied by Microtek and distributed by Davol. Further, Davol's proposed Drape is substantially equivalent to Microtek's preamendment Under Buttocks Drape with Fluid Collection Pouch, Catalog Number 4556. Both devices are designed to collect fluids during procedures where fluid needs to be collected and/or monitored. Attachment A of this Section summarizes the similarities and differences between the two products.

The 510(k) "Substantial Equivalence Decision Making Process (Detailed)" decision tree (see Exhibit 4) was utilized in making a determination of substantial equivalence. The answers to the decision tree questions lead to a determination of substantial equivalence.

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

Yes, both devices are intended for the collection of distention and irrigation fluids during diagnostic or operative hysteroscopy. Both devices include sterile hand cuffs to aid in proper placement of the drape under the patient. Both devices include a drainage port than can be opened and connected to suction.

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

Yes, both devices have the same technological characteristics, including design and materials. Both devices include a blue polyethylene under buttocks sheet with patient adhesive strip, a clear funnel-shaped polyethylene fluid collection pouch, a malleable wire support on the top outside edge of the pouch to keep it open during the procedure, a spunbonded nylon fabric filtration screen, and a drainage port. Both devices include a drainage port with a hinged cap, which can be opened to allow the drape pouch to be connected to suction. As noted above, the predicate product is currently supplied to Davol by Microtek, which Davol distributes with its HydroFlex HD Hysteroscopic Distention System (K982867).

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

Yes. The Drape subject of this submission and the predicate product are identical as summarized in the Comparison Chart, Attachment 6-1.

CONCLUSION:

Based upon the above information, the proposed Davol Drape is substantially equivalent to the Microtek Drape Davol currently distributes.

Lucinda L. Fox, Regulatory Affairs Associate — May 7, 1999 Date

Section 6.0 - Attachment 6-1

COMPARISON CHART		
Feature	**Davol Drape (This Submission)**	**Microtek Drape Currently Distributed by Davol**
Intended use is for the collection of distention and irrigation fluids during diagnostic or operative hysteroscopy.	Yes	Yes
Can be connected to suction	Yes	Yes
Blue Polyethylene Under Buttocks Sheet	Yes	Yes
Clear Funnel-Shaped Polyethylene Fluid Collection Pouch	Yes	Yes
Malleable wire support on the top outside edge of the pouch to keep pouch open during the procedure.	Yes	Yes
Spunbonded nylon fabric filtration screen inside the Fluid Collection Pouch	Yes	Yes
Drainage Port w/Hinged Cap	Yes	Yes
Hand Cuffs to aid in positioning the Drape	Yes	Yes
Patient Adhesive Strip	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 1999

Ms. Lucinda L. Fox
Regulatory Affairs Associate
Davol, Inc.
Subsidiary of C.R. Bard, Inc.
100 Sockanossett Crossroad
Cranston, Rhode Island 02920

Re: K991799
Davol® Hysteroscopy Pouch Drape and Tubing Set
Regulatory Class: II
21 CFR §884.1700/Procode: 85 HIG
Dated: August 19, 1999
Received: August 24, 1999

Dear Ms. Fox:

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 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

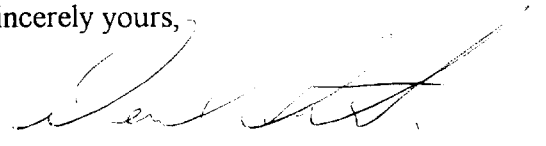
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. 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

510(k) Number: ~~Unknown~~ K991799

Device Name: Davol® Hysteroscopy Pouch Drape and Tubing Set

Indications for Use: The **Davol** Hysteroscopy Pouch Drape and Tubing Set is intended for the collection of distention and irrigation 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)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991799