K031213

Davol Inc.
Subsidiary of C. R. Bard, Inc.
100 Sockanossett Crossroad
P.O. Box 8500
Cranston, RI 02920
401 463-7000

APR 3 0 2003

DAVOL

Section 7.0
SUMMARY OF SAFETY AND EFFECTIVENESS FOR THE AQUASENS FLUID MONITORING SYSTEM 4000

A. Submitter's Name: Davol, Inc.
Address: Subsidiary of C.R. Bard Inc.
100 Sockanossett Crossroad
Cranston, RI 02920
Telephone: 401/463-7000 x 2642
Fax: 401/463-3845
Contact Person: Brian A. Kanerviko
Date of Preparation: February 18, 2003

B. 1. Trade Name: AquaSens Fluid Monitoring System 4000
2. Common Name: Hysteroscopic Fluid Monitoring Systems
3. Classification Name: Insufflator, Hysteroscopic; Fluid Monitoring Accessory (per CFR 884.1700)

C. Predicate Device Name
AquaSens Fluid Monitoring System 3000

D. Device Description
The major components of the AquaSens FMS 4000 are a load cell assembly which includes an IV pole structure for supporting irrigation bags and fluid suction canisters and an Electronic Control Unit (ECU) that acquires information from the load cell assembly to calculate and display fluid loss/gain based on changes in total weight after the system is initialized.

E. Intended Use
The Davol AquaSens Fluid Monitoring System 4000 is intended for use in gynecological surgical and diagnostic procedures. The system consolidates the supply and collection of irrigation fluids used during hysteroscopic procedures to distend the uterus and to clear the operative site of blood and debris. The system monitors irrigation fluid losses and indicates when such losses exceed a level pre-set by the surgeon.

F. Summary of Similarities and Differences in Technological Characteristics.

The predicate and proposed devices are designed to detect the loss of fluid weight by identifying discrepancies between fluid input and output by tracking changes in total

system fluid weight, then converting the information for display through the Electronic Control Unit. However, the predicate device is battery powered, whereas the proposed device is powered by either battery or electricity.

The proposed device has a re-designed way the user changes between the PAUSE and RUN modes. The predicate device utilized a single toggle bar on the top-rear of the Electronic Control Unit to change modes. In the proposed device this toggle bar is eliminated and replaced with two membrane buttons located on the front of the Electronic Control Unit labeled PAUSE and RUN. The proposed device will now allow the user to push the button to select the mode.

G. Performance Data

Laboratory testing was conducted to compare the proposed device to the predicate device. This testing consisted of a weight loss test in the AC, DC and low battery modes and switching characteristics of modes.

Underwriter Laboratories is currently conducting the necessary tests to ensure that this product will comply with the internationally harmonized standard UL 2601-1 for Medical Electrical Equipment. The test results from UL are currently pending, however the proposed device will not be marketed until all necessary test requirements under UL 2601-1 "General Electrical Requirement-Part 1: General Requirements for Safety" are satisfied.

H. Conclusion

Laboratory testing was conducted to compare the proposed device to the predicate device. This testing consisted of a weight loss test in the AC, DC and low battery modes. The test results indicated that both the proposed and predicate device performed within the given specifications under the same test conditions. Based on the above information it can be stated that the proposed AquaSens FMS 4000 is substantially equivalent to the predicate AquaSens FMS 3000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2003

C.R. Bard, Inc., Davol Division
% Mr. Robert Mosenkis
President
CITECH
Medical Device Testing and Consulting
5200 Butler Pike
PLYMOUTH MEETING PA 19462-1298

Re: K031213
Trade/Device Name: Davol AquaSens Fluid Monitoring System 4000
Regulation Number: 21 CFR 884.1700
Regulation Name: Hysterscopic insufflator
Regulatory Class: II
Product Code: 85 HIG
Dated: April 16, 2003
Received: April 17, 2003

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K031213

Device Name: Davol AquaSens Fluid Monitoring System 4000

Indications for Use:

The Davol AquaSens Fluid Monitoring System 4000 is intended for use in gynecological surgical and diagnostic procedures. The system consolidates the supply and collection of irrigation fluids used during hysteroscopic procedures to distend the uterus and to clear the operative site of blood and debris. The system monitors irrigation fluid losses/gains and indicates when such losses/gains exceed a level pre-set by the surgeon.

(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,
and Radiological Devices
510(k) Number K031213