K030307 1/2

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

FEB 13 2003

DAVOL

510(k) Summary of Safety and Effectiveness Information

A. Submitter Information:

Submitter's Name:	Davol Inc.
Address:	100 Sockanossett Crossroad Cranston, Rhode Island 02920
Phone Number:	(401) 463-7000, Ext. 2386
Fax Number:	(401) 463-3845
Contact Person:	Lucinda L. Fox
Date of Preparation:	December 13, 2002

B. Device Name:

Trade Name:	Davol® ArthroVent™ Outflow Tubing
Common/Usual Name:	Arthroscopic Accessory
Classification Name:	Arthroscopic Accessory

C. Predicate Product:

Stryker Suction Regulator (K963648)

D. Device Description:

The proposed Davol® ArthroVent™ Outflow Tubing allows the user to regulate suction during arthroscopic procedures. It consists of two flexible suction connectors, flexible polyvinyl chloride (PVC) inlet and outlet tubes, and a suction regulator assembly. The variable control suction regulator assembly contains a one-way flapper valve, kidney-shaped main vent hole and secondary air channels. The secondary channels provide an alternate airflow path if the main vent were inadvertently obstructed. When the main vent is open, the suction regulator assembly allows ambient air into the system to reduce suction delivered to the operative site. As a user convenience, the outlet tube has a pinch clamp to close off suction.

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E. Intended Use:

The **Davol ArthroVent** Outflow Tubing is designed to control the amount of suction during arthroscopic procedures by controlling the amount of ambient air entering the tubing set. It is for use with Davol's HydroFlex®-AD Arthroscopic Distention System (reference 0025800, 0025200, 0025210), Arthro-Flo® High Flow Irrigator (reference 0015000), and Gravity In-Flow Tubing Sets (reference 0088220, 0088240, and 0037870).

F. Summary of Similarities and Differences in Technological Characteristics, Performance, and Intended Use:

The **ArthroVent** Outflow Tubing and Stryker Suction Regulator are both designed to regulate suction by controlling the amount of ambient air entering the tubing sets. Both contain suction adapters, inlet and outlet tubes, and suction regulator mechanisms. Both products are made from similar materials and are sterile/single use devices.
The main difference between the **ArthroVent** Outflow Tubing and the Stryker Suction Regulator concerns the suction regulator mechanisms. The **ArthroVent** Outflow Tubing has a variable control suction regulator assembly with a kidney shaped vent and one-way flapper valve while the Stryker Suction Regulator has a tear drop shaped vent with a 7 setting, thumb controlled slide without a valve. Also, the **ArthroVent** Outflow Tubing has a strainer inside the suction regulator assembly to prevent clogging and a pinch clamp on the outlet tube to close off suction. Finally, the **ArthroVent** Outflow Tubing is limited to arthroscopic use while the Stryker Suction Regulator may be used in any procedure where suction control is desired.

G. Performance Data:

As with the Stryker Suction Regulator, the proposed **ArthroVent** Outflow Tubing will be compliant to the biocompability requirements pursuant to ISO 10993-1. Bench testing was performed to evaluate and compare the performance of the **ArthroVent** Outflow Tubing to the Stryker Suction Regulator using a simulated knee model and currently marketed inflow products. Results for both products were similar, which supports the substantial equivalence determination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2003

Davol, Inc.
c/o Ms. Michelle Weidman
Office Assistant Coordinator
Kema Medical
4377 County Line Road
Chalfont, Pennsylvania 18914

Re: K030307
Trade/Device Name: ArthroVent Outflow Tubing
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: January 28, 2003
Received: January 29, 2003

Dear Ms. Weidman:

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 such 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 (301) 594-4659. 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: Unknown

Device Name: Davol® ArthroVent™ Outflow Tubing

Indications for Use:

The Davol® ArthroVent™ Outflow Tubing is designed to control the amount of suction during arthroscopic procedures by controlling the amount of ambient air entering the outflow tubing set. It is for use with Davol's HydroFlex-AD Arthroscopic Distention System (reference 0025800, 0025200, 0025210), Arthro-Flo High Flow Irrigator (reference 0015000), and Gravity In-Flow Tubing Sets (reference 0088220, 0088240, and 0037870).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030307

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

(Optional Format 1-2-96)