MAY 17 2004

SECTION 6. K04 1641

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

JUL 01 2004

A. Submitter Information

Submitter's Name:	Davol, Inc.
Address:	Subsidiary of C. R. Bard, Inc. 100 Sockanossett Crossroad Cranston, RI 02920
Telephone:	401-463-7000 ext. 2263
Fax:	401-463-3845
Contact Person:	Suzanne LaScalza
Date of Preparation:	May 6, 2004

B. Device Name

Trade name:	Davol Delivery System
Common/Usual name:	Soft Tissue Prosthetic Delivery System
Classification name:	Endoscope and Accessories

C. Predicate Device Names

Trade name: Davol Surgical Mesh Delivery System (Davol Inc.)

Trade name: MedChem Surgical Delivery System (Davol Inc.)

D. Device Description

The proposed device is designed to roll a soft tissue prosthetic in a tight uniform manner and provide a protective tube through which the rolled prosthetic can be delivered into the abdomen. The proposed device consists of four distinct parts, a rolling tines/plunger assembly which is used to roll the soft tissue prosthetic, a hollow plastic delivery tube to hold the rolled prosthetic, a "T" handle which is placed over the tines to facilitate the plunging motion to deliver the prosthetic, and an optional switching stick which can be used to maintain the tissue path created by a trocar sleeve. The proposed device will be provided as a sterile device for single patient use. It will be available in two sizes, a small size for the delivery of smaller soft tissue prosthetics and a large size for the delivery of larger prosthetics.

E. Intended Use

The Davol Delivery System is intended to be used to facilitate the delivery of soft tissue prosthetics during the laparoscopic repair of soft tissue defects (e.g. hernia repair).

F. Technological Characteristics Summary

The Davol Delivery System and the predicate Davol device have the same intended use. Both devices are indicated to facilitate the delivery of soft tissue prosthetics, such as surgical mesh to the surgical site during laparoscopic soft tissue repair procedures (e.g. hernia repair).

The proposed device is similar to the two predicate devices in principle of operation and general design. The key differences are in the details of the device design.

In order to accommodate large soft tissue prosthetics, the large proposed device was designed with an inner diameter of 20 mm and an outer diameter of approximately 21 mm. The inner and outer diameters of the proposed device are similar to the large predicate MedChem device and fall within the size range of similar currently marketed devices.

The insertion end of the predicate devices could not be used in the proposed device since the open end of the predicate Davol device would be difficult to insert directly through an incision and even the slight taper of the predicate MedChem device would prevent the prosthetic from exiting the delivery tube. Instead, the insertion end of the proposed device is covered with a thin, flexible, rounded tip which is slit into three triangular leaves to form a valve. The rounded shape facilitates the entry of the delivery tube into the incision site while the slit valve allows the rounded tip to open wide enough to permit the prosthetic to exit. The insertion end of the proposed device does not affect the safety and effectiveness of the device since the rounded tip simply facilitates entry into the incision compared to an open insertion end.

The proposed device has an adjustable wing component on the delivery tube, which is not present in either of the two predicate devices. The wing component remains outside the body and provides a visual gauge of the insertion depth, as well as a place for the surgeon to brace against while pushing the soft tissue prosthetic through the delivery tube. This component does not adversely affect the safety and effectiveness of the device since the component remains outside the body and simply provides additional visual guide.

The switching stick of the proposed device is an optional component provided to maintain the pathway from the skin incision, through the tissue layers to the abdomen. Although neither predicate device includes a switching stick component, switching sticks, or exchange rods are sometimes packaged with currently marketed laparoscopic devices and commonly used to maintain the tissue pathway.

Preliminary bench testing was performed using several different large soft tissue prosthetics. Testing consisted of rolling the soft tissue prosthetic, inserting the

rolled prosthetic into the delivery device and plunging it out of the device onto a tabletop. Several trials were repeated after soaking the prosthetic in saline solution to simulate wet conditions. The results demonstrated that neither the prosthetics nor the proposed device exhibited damage after use. Further, the trials performed under wet conditions demonstrated that wetting the prosthetic facilitates ease of delivery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 01 2004

C.R. Bard, Inc.
c/o Mr. Robert Mosenkis
President
Citech
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

Re: K041641
Trade/Device Name: Davol Delivery System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: June 16, 2004
Received: June 17, 2004

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 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. 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 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

INDICATIONS FOR USE

510(k) Number (if known): K041641

Device Name: **Davol Delivery System**

Indications for Use: **The Davol Delivery System is intended to be used to facilitate the delivery of soft tissue prosthetics during the laparoscopic repair of soft tissue defects (e.g. hernia repair).**

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 K041641