K021736

JUL 16 2002

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS FOR THE VENTRALEX PATCH

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:	Brian A. Kanerviko
Date of Preparation:	May 1, 2002

B. Device Name

Ventralex Patch

C. Predicate Device Name

Trade name: Bard Composix Kugel Mesh (Davol Inc.)

D. Device Description

The proposed Ventralex Patch is a self-expanding, three layer device. Two layers consist of polypropylene mesh. The top layer of polypropylene mesh forms a positioning strap and pocket. The purpose of the strap and pocket is to facilitate placement, positioning and fixation of the device. After the device has been properly placed and attached, the positioning strap must be removed and properly discarded. The monofilament PET polymer "ring" is captured between the two layers of polypropylene mesh and adds stability to the device enabling greater simplicity and assurance in the proper placement. The third layer of the device is a single layer of expanded polytetrafluoroethylene (ePTFE) that is attached to the polypropylene mesh with an interlocking PTFE stitch pattern. The peripheral edge of the polypropylene mesh is heat sealed to the ePTFE layer.

E. Intended Use

The Ventralex Patch is intended for use in all hernia repairs requiring reinforcement with a nonabsorbable support material.

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

The Ventralex Patch and the predicate Composix Kugel Mesh are both intended for the use in all forms of hernia repair requiring reinforcement with a nonabsorbable support material.

Technologically, the proposed device has the same the same materials, and similar physical attributes and manufacturing methods.

The proposed device is designed to form a strap and pocket. The predicate device is designed to form just a pocket. The strap will be made of polypropylene. The purpose of the strap is to facilitate placement, positioning and fixation of the device. After the device has been properly placed and attached, the positioning strap must be removed and properly discarded.

G. Performance Data

Biocompatibility and bench testing have been completed and support the safety and effectiveness of the Ventralex Patch for its intended use.

As previously mentioned, the Composix Kugel predicate and the proposed Ventralex Patch devices use the same materials and similar manufacturing methods for production. The Ventralex Patch and the Composix Kugel Mesh have a single layer of expanded polytetrafluoroethylene (ePTFE) and is attached to the polypropylene mesh with an interlocking stitch using polytetrafluoroethylene (PTFE) monofilament. The peripheral edge of the polypropylene mesh is heat sealed to the ePTFE layer.

The biocompatibility test results show that the material used in the design and manufacture of the device are non-toxic and non-sensitizing to biological tissues consistent with their intended use. Laboratory test results demonstrate that the materials chosen and the design utilized in manufacturing the Ventralex Patch will meet the established specifications necessary for consistent performance during their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2002

C. R. Bard, Inc.
Brian A. Kanerviko
100 Sockanossett Crossroad
Cranston, Rhode Island 02920

Re: K021736
Trade Name: Ventralex Patch
Regulation Number: 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: May 23, 2002
Received: May 28, 2002

Dear Mr. Kanerviko:

We have reviewed your Section 510(k) premarket 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 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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,

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 (if known): K021736

Device Name: Ventralex Patch

Indications for Use: **Intended for the use in all forms of hernia repair requiring reinforcement with nonabsorbable support material.**

(Please do not write below this line – Continue on another page if needed)

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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 General, Restorative and Neurological Devices