

JUN - 2 2006

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS FOR THE MODIFIED COMPOSIX KUGEL MESH

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. 2389
Fax:	401-463-3845
Contact Person:	Robin M. Drago
Date of Preparation:	May 24, 2006

B. Device Name

XL Composix Kugel Mesh

C. Predicate Device Name

Trade name: Composix Kugel Mesh

D. Device Description

The modified XL Composix Kugel Mesh is a self-expanding, two-layered mesh with two extruded monofilament PET polymer "rings". The mesh is constructed of knitted polypropylene monofilament approximately 0.006" in diameter. The mesh is knitted to form a strong, porous, support material. The knit structure of the polypropylene mesh is identical to that of the predicate Composix Kugel Mesh product and allows for repair of the defect. The monofilament PET polymer "rings" add stability to the device enabling greater simplicity and assurance in the proper placement of the patch.

E. Intended Use

The modified XL Composix Kugel Mesh is intended for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects. It has the same intended use as the predicate Composix Kugel Mesh.

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

The overall design of the modified XL Composix Kugel is still equivalent to the predicate Composix Kugel describe in K003323. Both the modified XL Composix Kugel and the predicate Composix Kugel described in K003323 consist of two layers of polypropylene mesh and one layer of ePTFE and a PET recoil ring. The rings add stability to the device enabling greater simplicity and assurance in the proper placement of the device. K003323 covered product with both 0.030" and 0.042" diameter recoil rings. The current proposed design modifications involve using only the 0.030" ring in the XL Composix Kugel and increasing the strength specification of the ring weld in the XL size Composix Kugel codes. In order to achieve this a manufacturing change is being proposed which will increase the weld strength. Although the weld strength will be increased the ring will still have the same intended use (i.e. to add stability to the device enabling greater simplicity and assurance in the proper placement of the device.

G. Performance Data

Bench testing has been completed and supports the safety and effectiveness of the modified XL Composix Kugel Mesh for its intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2006

Davol, Inc.
% Ms. Robin M. Drago
VP, Regulatory and Clinical Affairs
100 Scokanossett Crossroad
Cranston, Rhode Island

Re: K061314

Trade/Device Name: Bard[®] Modified Extra Large Composix[®] Kugel[®]
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: May 10, 2006
Received: May 11, 2006

Dear Ms. Drago:

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 (240) 276-0115. 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,



for Mark N. Melkerson

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): K061314

Device Name: Bard® Modified Extra Large Composix® Kugel®
Hernia Patch

Indications For Use:

Bard Modified Extra Large Composix Kugel Hernia Patch is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K061314