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K082396

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SECTION 7.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

A. Submitter Information

Submitter's Name:	Davol Inc.
Address:	Subsidiary of C. R. Bard, Inc. 100 Crossing Boulevard Warwick, RI 02886
Telephone:	(401) 825-8588
Fax:	(401) 825-8765
Contact Person:	Stephanie Baker
Date of Preparation:	August 18, 2008

B. Device Name

Trade Name:	Davol Absorbable Fastener System
Common/Usual Name:	Staple, Implantable
Classification Name:	Staple, Implantable

C. Predicate Device Name

Trade name:	Permasorb Disposable Fixation Device (K060494)

D. Device Description

The Davol Absorbable Fastener System is designed to deliver an absorbable fastener into tissue or prosthesis during general surgery procedures such as hernia repair. The fastener system consists of an ergonomic handle with trigger, shaft and penetrating tip. The shaft is available in either a 36 cm length for laparoscopic use or an 18 cm length for open surgical procedures. The device is preloaded with 5, 15, or 30 absorbable fasteners. Each absorbable fastener contains threads for mesh and tissue delivery.

E. Intended Use

The Davol Absorbable Fastener System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

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

The Davol Absorbable Fastener System and the currently marketed Permasorb Disposable Fixation Device are both indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

In addition, both products are similar in technological characteristics and performance. Both devices have the same basic components including a handle and shaft designed to deliver a fastener. Both devices use similar fixation technology to deliver the fasteners by compressing a trigger. The fasteners are manufactured from the same polymer material, poly (D, L) lactide.

The proposed device and the predicate device differ in the details of the device design. The proposed device has a gun shaped handle and fasteners that are screw-like while the predicate device has a T-shaped handle and fasteners that are tack-like.

G. Performance Data

Biocompatibility testing on the Davol Absorbable Fastener System fastener has been completed. The biocompatibility test results show that the material used in the design and manufacture of the components of the proposed device are non-toxic and non-sensitizing to biological tissues consistent with its intended use.

The Davol Absorbable fasteners were tested in vitro in a hernia repair model and in vivo in an animal model to confirm the mechanical strength of the repair over time as compared to the predicate device.

Additional in vitro laboratory tests were conducted to characterize material degradation over time.

All test results demonstrate that the material chosen, the manufacturing process, and the design utilized for the Davol Absorbable Fastener System met the established specifications necessary for consistent performance during its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 2 2009

Davol Inc.
% C.R. Bard Inc.
Ms. Stephanie Baker
Senior Regulatory Affairs Associate
100 Crossing Boulevard
Warwick, Rhode Island

Re: K082396
Trade/Device Name: Davol Absorbable Fastener System
Regulation Number: 21 CFR 878.4750
Device Name: Implantable Staple
Regulatory Class: II
Product Code: GDW
Dated: December 16, 2008
Received: December 17, 2008

Dear Ms. Baker:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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 Statement

510(k) Number (if known): K082396

Device Name: **Davol Absorbable Fastener System**

Indications for Use: The **Davol Absorbable Fastener System** is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

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

FOR M. MELKERSON

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

510(k) Number K082396