K092483
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SECTION 7.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

A. Submitter Information

DEC 18 2009

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:	Kevin G. Stevens
Date of Preparation:	August 12, 2009

B. Device Name

Trade Name:	**Bard PermaFix Fixation System**
Common/Usual Name:	Staple, Implantable
Classification Name:	Staple, Implantable

C. Predicate Device Name

Trade name:	Davol Absorbable Fastener System (K082396)

D. Device Description

The Bard PermaFix™ Fixation System is disposable, single-use system designed to deliver a permanent fastener into tissue or prosthesis during general surgery procedures such as hernia repair. The fastener delivery 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 a 20 cm length for open surgical procedures. The device is preloaded with 15 or 30 permanent fasteners. Each permanent fastener contains threads for mesh and tissue delivery.

E. Intended Use

The Bard PermaFix Fixation 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 Bard PermaFix Fixation System and the currently marketed Davol SorbaFix Fastener System (Predicate 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. Indeed, both devices are the same design and have fasteners that are the same shape and configuration. Both devices use the same fixation technology to deliver the fasteners by compressing a trigger. The salient difference between the SorbaFix Fastener System and the PermaFix Fastener System is the choice of material used in the fastener. The PermaFix uses a permanent, biocompatible material versus the absorbable poly (D,L) lactide material used in the SorbaFix Absorbable Fastener System.

G. Performance Data

The biocompatibility test results show that the material used in the design and manufacture of the components of the proposed device are compatible with biological tissues consistent with its intended use. In addition, a material characterization has been performed to demonstrate that this material is similar in composition to other implantable medical devices. This material is well characterized and has been used for several years in the medical device industry.

The Bard PermaFix fasteners were tested in vitro in a hernia repair model to confirm the mechanical strength of the repair as compared to the predicate device.

All test results demonstrate that the material chosen, the manufacturing process, and the design used for the Bard PermaFix Fixation System met the established specifications necessary for consistent performance for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC 18 2009

C.R. Bard, Inc.
% Davol, Inc.
Mr. Kevin Stevens
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K092483
Trade/Device Name: BARD PERMAFIX FIXATION SYSTEM
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: December 11, 2009
Received: December 14, 2009

Dear Mr. Stevens:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092483

Indications for Use Statement

510(k) Number (if known):

Device Name: **BARD PERMAFIX FIXATION SYSTEM**

Indications for Use: The **BARD PERMAFIX FIXATION 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)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092483