510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

MAY 2 4 2011

This 510(k) Summary is provided per the requirements of section 807.92(c).

Submitter Information

Submitter's Name:	Davol, Inc., Subsidiary of C. R. Bard, Inc.
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Device Name

Trade Name:	**SorbaFix™ Absorbable Fixation System** **PermaFix™ Fixation System**
Device Common Name:	Staple, Implantable
Classification Code:	Class II, §878.4750, Product Code GDW

Predicate Device Names

- K082396 Davol Absorbable Fastener System, cleared on January 02, 2009
- K092483 PermaFix Fixation System, cleared on December 18, 2009

Device Description

The proposed **SorbaFix Absorbable Fixation System** is a sterile single use device that delivers either 15 or 30 synthetic absorbable fasteners. The fasteners are dyed with D & C Violet No. 2 in accordance with 21 CFR 74.1602. The shaft of the SorbaFix Absorbable Fixation System is 36 cm in length, including a piloting tip. The fasteners are 6.7 mm in length and are manufactured from Poly (D, L)-lactide. The fixation instrument shafts have an outer diameter of 5 mm, and may be used in open procedures or with most 5 mm trocars in laparoscopic procedures. The device includes a fastener gauge located on the back of the handpiece for user convenience only. The gauge will move right to left as the fasteners are deployed and indicates the approximate level of fasteners remaining in the device.

The proposed **PermaFix Fixation System** is a sterile single use device that delivers

- have the same implantable fastener design and similar delivery system design;
- have the same materials as the predicate device:
- have the same shelf life;
- use the same sterilization method; and
- are packaged and sterilized using the same materials and processes.

The contraindication statement was expanded to the proposed SorbaFix and PermaFix IFU's as a remedial action taken following the internal investigation of the medical device reports from one incidence on one patient during one procedure. The proposed **SorbaFix Absorbable Fixation System** and **PermaFix Fixation System** are made from materials identical to their respective predicates (SorbaFix K082396 and PermaFix K092483). The SorbaFix fasteners are composed of an absorbable polymer material, i.e. poly (D, L) lactide, dyed with D&C Violet No. 2 in accordance with 21 CFR 74.1602. The PermaFix fasteners are manufactured from a non-absorbable acetal copolymer material. The other patient contacting components in the delivery system are all made from the same stainless steel as that of the predicates.

Full biocompatibility testing was conducted on both the predicate SorbaFix and PermaFix fasteners, the long term implants, in accordance with the ISO 10993 series requirements. The results of these tests were submitted under K082396 (Davol Absorbable Fastener System) and K092483 (PermaFix Fixation System) respectively. The biocompatibility data has ensured that the devices are safe for their intended use.

No further biocompatibility testing is necessary because the proposed devices incorporate the same materials as their respective predicates.

Other modifications covered under this Special 510(k) include:

- labeling changes to remove the word "laparoscopic" from the 36 cm shaft devices for clarity purposes;
- Modification of component dimensional specifications in the delivery system by removing the location of the clutch component from the end of the drive train towards the trigger to improve the drive mechanism;
- Addition of a fastener gauge to the back of the ergonomic handle for user convenience.

Tables summarizing the similarities and differences between the proposed devices and their respective predicates are provided in **Section 15.0**.

Substantial Equivalence:

Design verification and validation testing were conducted and demonstrated that the proposed **SorbaFix and PermaFix** met the requirements set up in the product performance specifications for their respective predicate devices (SorbaFix K082396 and

PermaFix K092483). A summary of the design control activities are provided in **Section 18.0** of this Premarket Notification.

In summary, based on the performance data and the substantial equivalence comparison tables (reference **Section 15.0**), Davol Inc. believes that the proposed **SorbaFix Absorbable Fixation System and PermaFix Fixation System** are substantially equivalent to their respective predicates (SorbaFix K082396 and PermaFix K092483).

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

C. R. Bard, Inc.
% Davol, Inc.
Ms. Zheng Liu
Regulatory Affairs Project Manager
100 Crossings Boulevard
Warwick, Rhode Island 02886

MAY 24 2011

Re: K111153
Trade/Device Name: SorbaFix™ and PermaFix™ Absorbable Fixation Systems
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: April 22, 2011
Received: April 25, 2011

Dear Ms. Liu:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

K111153
p. 1 of 1

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name:	**SorbaFix™ Absorbable Fixation System**
Indications for Use:	The **SorbaFix Absorbable 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.
Device Name:	**PermaFix™ Fixation System**
Indications for Use:	The **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__ 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)

David Krause for MKM

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

510(k) Number K111153