DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 11, 2017

C.R. Bard Incorporated
Ms. Katherine Earle
Regulatory Affairs Specialist
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K163698
Trade/Device Name: Optifix Open Absorbable Fixation System - 20 Absorbable Fasteners
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: December 27, 2016
Received: December 29, 2016

Dear Ms. Earle:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163698

Device Name
OptiFix™ Open Absorbable Fixation System

Indications for Use *(Describe)*
The OptiFix™ Open Absorbable Fixation System is indicated for the fixation of surgical mesh to tissues during open surgical procedures, such as hernia repair.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5 510(k) Summary

I. SUBMITTER

Davol Inc.
100 Crossings Boulevard
Warwick, RI 02886

Contact Person: Katherine Earle
Regulatory Affairs Specialist
Phone: (401) 825-8450
Fax: (401) 825-8765
E-mail: katherine.earle@crbard.com

Date Prepared: December 27, 2016

II. DEVICE

Name of Device:	OptiFix™ Open Absorbable Fixation System
Product Code:	0113320
Common or Usual Name:	Implantable Staple
Classification Name:	Implantable Staple (21 CFR §878.4750)
Regulatory Class:	II
Product Code:	GDW

III. PREDICATE DEVICE

The predicate device for this submission is the OptiFix™ Absorbable Fixation System (K142873), cleared March 12, 2015***;*** marketed by Davol, Inc. This predicate has not been subject to a design-related recall.

The reference devices used in this submission are the following:

- Davol Absorbable Fastener System – SorbaFix™ (K082396), cleared January 2, 2009
- OptiFix™ Absorbable Fixation System (K132134), cleared December 2, 2013

IV. DEVICE DESCRIPTION

The OptiFix™ Open Absorbable Fixation System, hereinafter referred to as "OptiFix™ Open", is a sterile (via gamma) single use device that is comprised of a deployment component and an absorbable fastener component. The device delivers 20 synthetic absorbable fasteners via a curved shaft. The shaft of the OptiFix™ Open Absorbable Fixation System is 27cm in length. The fasteners are 6.7mm in length, are manufactured from Poly (D, L)-lactide and are dyed with D & C Violet No. 2.

V. INDICATIONS FOR USE

The OptiFix™ Open Absorbable Fixation System is indicated for the fixation of surgical mesh to tissues during open surgical procedures, such as hernia repair.

The Indications for Use statement for the proposed device falls within the indications for use of the predicate device. Therefore, the proposed and predicate devices have the same intended use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The fixation of surgical mesh to tissues during open surgical procedures, such as hernia repair using the mechanical actuation (trigger) force to guide the fastener and launch the implant is the operating principle for both the proposed and predicate devices.

The proposed and predicate devices are based on the following similar elements:

- Deployment component – mechanical component used to position and launch the fastener (implant) into tissue, consisting of a shaft connected to an ergonomic handle and integrated user-controller trigger.
- Fastener component –absorbable component composed of Poly (D, L)-lactide, used to fixate surgical mesh to tissue.

The following differences exist between the proposed and predicate devices:

- The handle configuration of the proposed device is rotated 180° compared to the predicate device
- The deployment shaft of the proposed device is shorter in length (27 cm) compared to the deployment shaft of the predicate device (39cm).
- The deployment shaft of the proposed device has a 35° permanent angle, whereas the predicate device has a straight deployment shaft.

VII. PERFORMANCE DATA

The following performance data is provided in support of the substantial equivalence determination.

Performance standards
No performance standards have been established for this device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

Biocompatibility testing
The biocompatibility evaluation for the OptiFix™ Open device was conducted in accordance with FDA Guidance, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*, June 16, 2016; and International Standard ISO 10993-1 "*Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process*," as recognized by FDA.

The absorbable fasteners are determined to be long term implants (>30 days) and are supported by the biocompatibility testing listed below.

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Single-does Systemic Toxicity
- Rabbit Pyrogenicity
- 14-Day Repeat Dose Intravenous Toxicity
- Genotoxicity
- Chronic Toxicity, 13 weeks
- Implantation, 4 weeks
- Implantation, 8 weeks
- Implantation, 12 weeks
- Implantation, 26 weeks
- Implantation, 52 weeks

The deployment component of the proposed OptiFix™ Open device is determined to be tissue contacting for a duration of less than 24 hours, and has been supported by the biocompatibility testing as listed below.

- Cytotoxicity

All samples tested met the acceptance criteria and the proposed OptiFix™ Open device is biocompatible for its intended use.

Electrical safety and electromagnetic compatibility (EMC)
The proposed OptiFix™ Open device is not an electro-mechanical medical device nor is it a medical system, therefore this section does not apply.

Software Verification and Validation Testing
The proposed OptiFix™ Open device does not contain software; therefore this section does not apply.

Product Testing
The following non-clinical tests were completed for the proposed and predicate device. The OptiFix™ Open device passed all the test requirements and demonstrated substantial equivalence to the test results of the predicate device.

- Performance and Functional testing of the OptiFix™ Open device
    - Actuation (trigger) Torque
    - Fastener Deployment
    - Fastener Gap Height
    - Ball Burst Testing
    - Single Fastener Pullout (Pluck) Force

- Resorption Profile Assessment of the OptiFix™ Open fastener
    - Physical Properties
    - Mechanical Shear Force

All samples tested met the established acceptance criteria.

Animal Study
Animal studies were not performed on the proposed device for this submission. Based on identical materials and substantially equivalent mechanical strengths measured at the bench level, the in vivo safety and performance of the proposed device was evaluated via the animal and histological studies conducted on the reference devices; Davol Absorbable Fastener System – SorbaFix™ (K082396) and OptiFix™ Absorbable Fixation System (K132134), which were used to support the predicate OptiFix™ Absorbable Fixation System (K142873).

Clinical Studies
Clinical studies were not performed for the submission of this proposed device nor were clinical studies performed for the predicate device.

VIII. CONCLUSIONS

The proposed OptiFix™ Open device is substantially equivalent to the legally marketed predicate device for the following reasons:

A) The same intended use as the predicate device.
B) Similar technological characteristics as the predicate device such as: the fastener delivery system, deployment device trigger, and the fastener dimensions, shape/design and material.
C) The same principle of operation.

The comparative analysis, see Table 5-1 below, as well as the bench and preclinical testing results demonstrate that the proposed OptiFix™ Open device performs as intended and is substantially equivalent to the predicate device that is currently marketed for the same intended use.

Table 5-1: Device Substantial Equivalence – General Characteristics

Device Features	**Proposed device OptiFix™ Open**	**Predicate device OptiFix™ (K142873)**
Intended Use	Same as predicate	Soft tissue fixation
Indication for Use	Indicated for the fixation of surgical mesh to tissues during open surgical procedures, such as hernia repair.	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 Features	**Proposed device OptiFix™ Open**	**Predicate device OptiFix™ (K142873)**
Fastener Material	Same as predicate	Poly (D,L) – Lactide
Fastener Violet Dye	Same as predicate	D & C Violet No. 2 conforms to 21 CFR § 74.1602(a)(1) and (b)
Fastener Body Contact	Same as predicate	Long term implant (>30 days) contacting tissue and/or bone
Fastener Shape/Design	Same as predicate 	Push Tack with retention features on end 
Overall Fastener Dimensions	Same as predicate	6.7mm overall fastener length Fastener head: 3.7 mm length; 3.5 mm thickness
Fastener Manufacturing Method	Same as predicate	Injection - Molded
Fastener Absorption Time	Same as predicate	360 days
Fastener Quantity per Device	20 fasteners	15 & 30 fasteners
Fastener Delivery System	Same as predicate	Push – Impact tube pushes fasteners forward over a guidewire
Deployment Component Configuration		
Deployment Component Shaft Length	27cm in length	39cm in length
Deployment Component Shaft Angle	35°	None
Deployment Component Body Contact	Same as predicate	Transient use – Less than 24 hour duration
Device Sterilization	Same as predicate	Gamma Irradiation (25 – 40 kGy)

Device Features	**Proposed device OptiFix™ Open**	**Predicate device OptiFix™ (K142873)**
Device Packaging	Device is placed into a PETG (Polyethylene terephthalate Glycol-modified) thermoformed tray which is inserted into a foil pouch, sealed and placed into an SBS (Solid Bleached Sulfate) paperboard printed shelf carton.	Device is placed into an SBS (Solid Bleached Sulfate) cardboard insert which is inserted into a foil pouch, sealed and then placed into an SBS (Solid Bleached Sulfate) paperboard printed shelf carton.