DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 31, 2017

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

Re: K170278
Trade/Device Name: Optifix AT Absorbable Fixation System With Articulating Technology - 30 Fasteners, Optifix AT Absorbable Fixation System With Articulating Technology - 15 Fasteners

Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: April 28, 2017
Received: May 1, 2017

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,

Jennifer R. Stevenson -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
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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)*
K170278

Device Name
OptiFix AT Absorbable Fixation System with Articulating Technology - 30 Fasteners, OptiFix AT Absorbable Fixation System with Articulating Technology - 15 Fasteners

Indications for Use *(Describe)*
The OptiFix AT Absorbable Fixation System with Articulating Technology 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.

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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510(k) Summary

I. SUBMITTER

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Date Prepared: May 30, 2017

II. DEVICE

510(k) Number:	K170278
Name of Device:	OptiFix™ AT Absorbable Fixation System with Articulating Technology
Common or Usual Name:	Implantable Staple
Classification Name:	Implantable Staple (21 CFR §878.4750)
Regulatory Class:	II
Product Code:	GDW

III. PREDICATE DEVICE

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

The secondary predicate device for this submission is the Medtronic Covidien AbsorbaTack™ Absorbable Fastener System (K123109), cleared January 27, 2012.

IV. DEVICE DESCRIPTION

The OptiFix™ AT Absorbable Fixation System with Articulating Technology, hereinafter referred to as "OptiFix™ AT", is a sterile (via gamma) single use device that is comprised of a deployment component and an absorbable fastener component. Two different product ordering codes are to be packaged for distribution; each contains the same ergonomically designed deployment device. The variation will be the number of preloaded fasteners; either 15 or 30. The deployment shaft of the OptiFix™ AT device is 37cm in length and designed for use with 5mm trocars. The tip of the shaft can be articulated and the handle of the device can be rotated 360 degrees to facilitate access for fixation during surgery. The fasteners are designed with retention features and are manufactured from Poly (L-lactide-co-glycolide) and are dyed with D & C Violet No. 2 (≤0.15% by weight).

V. INDICATIONS FOR USE

The OptiFix™ AT Absorbable Fixation System with Articulating Technology 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.

The Indications for Use statement for the subject device is identical to that of the primary predicate device (OptiFix™-K142873), and similar to that of the secondary predicate device (AbsorbaTack™-K123109). The proposed and predicate devices are all intended for the fixation of surgical mesh/prosthetic to tissue during open or laparoscopic surgical procedures, such as hernia repair.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The fixation of surgical mesh/prosthetic to tissue during open or laparoscopic surgical procedures, such as hernia repair, using a mechanical actuation force to guide and launch the fastener implant is the operating principle for 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
- Fastener component –absorbable component composed of well-characterized absorbable polymer, used to fixate surgical mesh to tissue.
    - The fastener shape/design and dimensions of the subject device are similar to that of the primary predicate device (OptiFix™-K142873).
    - The fastener material for the subject device (Poly(l-lactide-co-glycolide)) is identical to that of the secondary predicate device (AbsorbaTack™-K123109).

The following differences exist between the proposed and predicate devices:

- The handle configuration of the proposed device can be rotated 360° and the deployment shaft articulated to facilitate fixation, unlike the predicate devices which have no articulation in the deployment shaft and a static handle.
- The deployment shaft of the proposed device is shorter in length (37 cm) compared to the deployment shaft of the primary predicate device (39cm).
- The proposed absorbable fastener has minor geometric differences and is composed of a different material (Poly(L-lactide-co-glycolide)) than the primary predicate absorbable fastener (Poly(D,L)-lactide).

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™ AT 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 proposed device is supported by the biocompatibility testing listed below.

- Cytotoxicity
- Sensitization
- Intracutaneous (Irritation)
- Systemic Acute Toxicity
- Sub-Chronic Toxicity (13 weeks)
- Chronic Toxicity (26 weeks)
- Genotoxicity – Mouse Peripheral Blood Micronucleus Study
- Genotoxicity – Bacterial Reverse Mutation Study
- Genotoxicity – Mouse Lymphoma Assay
- Implantation – 4, 8, 12, 26, 39, 52, 77 weeks
- Pyrogenicity

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

Electrical safety and electromagnetic compatibility (EMC)
The proposed OptiFix™ AT 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™ AT device does not contain software; therefore this section does not apply.

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

- Performance and Functional testing of the OptiFix™ AT device
    - Actuation (trigger) Torque
    - Fastener Deployment
    - Fastener Gap Height
    - Ball Burst Testing
- Mesh compatibility testing of the OptiFix™ AT device
- Resorption Profile of the fastener
    - *In-Vitro* Degradation
    - *In-Vitro* to *In-Vivo* Correlation

All samples tested met the established acceptance criteria.

Animal Study
The safety and feasibility of the OptiFix™ AT device was evaluated by animal and histological evaluation of the tissue in the treatment fixated areas. The evaluation used the secondary predicate, AbsorbaTack™ (K123109), as a control since the fastener is composed of the same material, Poly (L-lactide-co-glycolide) in an 82%/18% molar ratio, and has the same intended use as the OptiFix™ AT device. The study demonstrated that the OptiFix AT device can safely, approximate soft tissue and fixate surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair. The following endpoints were evaluated:

- Mesh contracture
- Fastener seating properties
- Tissue in-growth (T-peel analysis)
- Host inflammatory/fibrotic response

Clinical Studies
Clinical studies were not performed for the submission of this proposed device nor were clinical studies performed for the primary predicate device (OptiFix-K142873).

VIII. CONCLUSIONS

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

A) The same intended use as the primary predicate device.
B) Similar technological characteristics as the primary predicate device such as: Fastener shape/design, trigger handle, penetration depth, and shaft length. The differences in technology do not adversely impact the safety and performance of the device.
C) Identical principle of operation to deliver fasteners perpendicular to the tissue plane.

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

Table 5-1: Device Substantial Equivalence – General Characteristics

Device Features	**Proposed device OptiFix™ AT**	**Predicate device OptiFix™ (K142873)**
Intended Use	Identical to predicate	Soft tissue fixation
Indication For Use	Identical to predicate	Indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.
Fastener Material	Resorbable Polymer Poly(L-lactide-co-glycolide) (PLG)	Resorbable Polymer Poly (D,L) Lactide
Fastener Violet Dye	Identical to predicate	D & C Violet No. 2 (≤0.15% by weight) conforms to 21 CFR §74.1602
Fastener Body Contact	Identical to predicate	Long term implant (>30 days) contacting tissue and/or bone
Fastener Shape/Design	Push Tack with retention features on end; nested tip 	Push Tack with retention features on end 

Device Features	**Proposed device OptiFix™ AT**	**Predicate device OptiFix™ (K142873)**
Fastener Dimensions	7.1 mm overall fastener length Fastener head: 3.5 mm diameter	6.7 mm overall fastener length Fastener head: 3.7 mm diameter
Fastener Manufacturing Method	Identical to predicate	Injection-Molded
Fastener Absorption Time	Identical to predicate	360 days
Fastener Quantity per Device	Identical to predicate	15 & 30 fasteners
Fastener Delivery System	Identical to predicate	Push – Impact tube pushes fasteners forward over a guidewire
Deployment Component Handle design	Pistol/Gun shape with 360 degree rotation option	Pistol/Gun shape with no rotation
Deployment Component Shaft	37 cm in length, 6 cm of articulation	39 cm in length, no articulation
Deployment Component Configuration		
Deployment Component Body Contact	Identical to predicate	Transient use – Less than 24 hour duration
Device Sterilization	Identical to predicate	Gamma Irradiation (25 - 40 kGy)
Device Packaging	Identical to predicate	Device is placed into an SBS cardboard insert which is inserted into a foil pouch, sealed and then placed into an SBS paperboard printed shelf carton.