July 16, 2019

Davol Inc., Subsidiary of C.R. Bard
Angelica Hutchison
Regulatory Affairs Specialist
100 Crossings Blvd
Warwick, Rhode Island 02886

Re: K191287
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: June 14, 2019
Received: June 17, 2019

Dear Angelica Hutchison:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Nina Mezu-Nwaba, PharmD., MPH., MSc,
CAPT., United States Public Health Service
Assistant Director (Acting), Plastic Surgery Implant Devices Team
Division of Infection Control and Plastic Surgery Devices
Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191287

Device Name
OptiFix AT Absorbable Fixation System with Articulating Technology

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5 510(k) Summary

I. SUBMITTER

Davol Inc., a Subsidiary of C.R. Bard, Inc.
100 Crossings Boulevard
Warwick, RI 02886

Contact Person: Angelica Hutchison
Regulatory Affairs Specialist

Phone: (401) 825-8537
Fax: (401) 825-8765
E-mail: angelica.hutchison@bd.com

Date Prepared: May 10, 2019

II. DEVICE

Name of Device:	OptiFix™ AT Absorbable Fixation System
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™ AT Absorbable Fixation System with Articulating Technology (K170278) cleared May 31, 2017. The predicate device has not been previously released to market and has not been subject to a design-related recall.

The reference device used in this submission is OptiFix™ Absorbable Fixation System (K142873), cleared on March 12, 2015; marketed by Davol Inc. This reference device has not been subject to a design related recall.

IV. DEVICE DESCRIPTION

The OptiFix™ AT Absorbable Fixation System with Articulating Technology, herein after 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. The device is available in either 15 or 30 preloaded fasteners. 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 and glycolide) and are dyed with D&C Violet No. 2.

The proposed device description is identical to what was previously cleared for the predicate device via K170278.

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 and laparoscopic

surgical procedures, such as hernia repair. This indication is identical to the predicate device, OptiFix™ AT, K170278.

The intended use of the OptiFix™ AT device as covered by this Special 510(k) submission is identical to the predicate device, OptiFix™ AT, K170278. Both devices are intended for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

VI. SUMMARY COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed OptiFix™ AT device has the same indications for use, fundamental scientific technology and performance characteristics as the original OptiFix™ AT device, cleared via K170278. The following technological characteristics of the OptiFix™ AT device are the same as the predicate device: device materials, delivery system design, principle of operation, biocompatibility, and sterilization. Modifications have been made to K170278 OptiFix™ AT device in order to optimize device performance. These modifications, which are the subject of this submission, are as follows:

- Updated packaging configuration
- The Instructions for Use (IFU) was updated for clarification and to provide additional information relating to changes to the device user interface
- Minor dimensional and manufacturability changes to the fastener and delivery system to optimize fastener deployment
- Removal of the fastener level indicator

Table 5-1: Summary Comparison of Predicate OptiFix™ AT (K170278) and Proposed OptiFix™ AT - General Characteristics

Device Features	**OptiFix™ AT (Predicate Device) K170278**	**OptiFix™ AT (Proposed Device)**
Intended Use	Soft tissue fixation	Same
Indication for Use	Indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.	Same
Fastener Material and Dye	Poly(L-lactide-co-glycolide) (PLG) D&C Violet No. 2 Conforms to 21 CFR §74.1602	Same
Fastener Body Contact	Long term implant (>30 days) contacting tissue and/or bone	Same
Fastener Shape/Design and Dimensions	Overall fastener length: 7.1 mm Fastener head: 3.5 mm diameter	Same
Fastener Absorption Time	360 days	Same

Device Features	OptiFix™ AT (Predicate Device) K170278	OptiFix™ AT (Proposed Device)
Fastener Quantity per Device	15 & 30 fasteners	Same
Deployment Component Handle Design	Pistol/Gun shape with 360 rotation option	Same
Deployment Component Shaft	37 cm in length, 6 cm of articulation	Same
Device Sterilization	Gamma Irradiation	Same
Device Packaging Configuration	Primary Packaging: Device is placed into a cardboard insert which is inserted into a foil pouch. Secondary Packaging: Placed into a paperboard printed shelf carton.	Primary Packaging: Device is placed into a PETG tray which is inserted into a foil pouch. Secondary Packaging: Same.

VII. PERFORMANCE DATA

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 OptiFix™ AT device was evaluated and successfully completed biocompatibility testing in accordance with the FDA Guidance "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." 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.

Product Testing
The following non-clinical tests were completed for the proposed OptiFix™ AT device:

- Design Verification Testing
- Design Validation Testing

The proposed OptiFix™ AT device passed all the test requirements and demonstrated that the proposed device design meets product specifications and intended uses. All samples tested met the established acceptance criteria.

Package Integrity Testing
Package Qualification testing has been completed for the proposed OptiFix™ AT device in accordance with the following FDA consensus standards: ISO 11607-1+A1:2014 "*Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems*" and ISO 11607-2:2006+A1:2014 "*Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing, and assembly processes*".

Animal Study
The proposed OptiFix™ AT device has the same fundamental scientific technology, with the same performance specifications as the predicate device, and the absorbable fastener component is identical in material and design. No additional animal studies were performed in support of this submission.

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

VIII. CONCLUSIONS

The results of verification and validation testing demonstrate that the proposed OptiFix™ AT device is sustainably equivalent to the predicate device that has been previously cleared for the same intended uses.