Covidien
Megha Patel
Senior Regulatory Affairs Specialist
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K231240
Trade/Device Name: MaxTack™ Motorized Fixation Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Staple, Implantable
Regulatory Class: Class II
Product Code: OCW, GDW
Dated: August 10, 2023
Received: August 10, 2023

Dear Megha Patel:

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 and Part 809); 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,

Francisco Delgado -S
2023.09.08 16:45:11 -04'00'

for Mark Trumbore, Ph.D.
Assistant Director, THT4A1: Robotically-Assisted Surgical Devices Team
DHT4A: Division of General Surgery Devices
OHT4: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231240

Device Name
MaxTack™ Motorized Fixation Device

Indications for Use *(Describe)*
The device is indicated for use in fixation of prosthetic material to soft tissue in minimally invasive ventral and minimally invasive groin hernia repair procedures.

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.

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510(k) Summary

DATE PREPARED:
April 28, 2023

SUBMITTER:
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North Haven, CT 06473 USA

CONTACT PERSON:
Megha Patel, MS-RA
Sr. Regulatory Affairs Specialist
Telephone: (917) 664-9611

IDENTIFICATION OF DEVICE:

Proprietary/Trade Name:	MaxTack™ Motorized Fixation Device
Classification Name:	Staple, Implantable
Regulations Number:	21 CFR 876.1500; 21 CFR 878.4750
Device Class:	Class II
Product Codes:	OCW; GDW
Review Panel:	General and Plastic Surgery
Common Name:	Surgical Stapler

PREDICATE DEVICE:

	Predicate
510(k) Number	K090470
Proprietary/Trade Name	AbsorbaTack™ Absorbable Fixation Device (ABSTACK30)
Classification Name	Staple, Implantable
Regulation Number	21 CFR 876.1500; 21 CFR 878.4750
Device Class	Class II
Product Code	OCW; GDW
Review Panel	General and Plastic Surgery
Common Name	Surgical Stapler

DEVICE DESCRIPTION:
The MaxTack™ Motorized Fixation Device is a single-use, sterile device that contains 30 absorbable tacks, preloaded into a standard shaft. The device is designed for introduction and use through a 5 mm or larger cannula. The device's tacks are constructed of an absorbable synthetic polyester copolymer derived from lactic and glycolic acid. The first 25 tacks are dyed with D&C Violet No. 2. The last 5 tacks are dyed with D&C Green No. 6. to serve as an indicator of low tack count to the user. The distal end of the shaft has a mesh manipulation/grip feature that may be used to facilitate positioning of the mesh.

The device is intended for use in a sterile operating room environment in surgical procedures where fixation of prosthetic material, such as mesh, to soft tissues is indicated. This device is designed, tested, and manufactured for single patient use only. Intended users are healthcare professionals who have been trained in applicable surgical procedures and approaches involving fixation devices prior to employing this device.

INDICATIONS FOR USE:
The device is indicated for use in fixation of prosthetic material to soft tissue in minimally invasive ventral and minimally invasive groin hernia repair procedures.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:
MaxTack™ Motorized Fixation Device, as implied by the product name, is a motorized hernia fixation technology that can deploy up to 30 absorbable tacks. The advantages of the device, such as push-button operations and in-line handle, offer an ergonomic advantage, allowing for each tack to be deployed with equivalent force.

Following changes to the technological characteristics have been made compared to the predicate – K090470, AbsorbaTack™ Absorbable Fixation Device (ABSTACK30):

- The tacks are delivered through a drive shaft assembly rotated by a motor that is controlled via software through a printed circuit board assembly (PCBA), housed in the handle. The device is powered by two 9V alkaline batteries in parallel.
- Change in tack design as compared to predicate, to maintain/increase current fixation strength at both perpendicular and non-perpendicular tack firings. Also, the last five tacks that will be fired by the subject device are dyed with a different colorant (D&C Green No. 6) as an indicator of low tack count to the user.
- The distal end of the shaft of the subject device will have a mesh manipulation/grip feature that may be used to facilitate positioning of the mesh.

The design differences were found to have no impact on safety or effectiveness. This was established through applicable design verification and validation activities that showed continued conformance to applicable technical design specifications and performance.

SUBSTANTIAL EQUIVALENCE:
The below table summarizes the similarities and differences between the subject and predicate devices.

Feature	Subject Device (MAXTACK30)	Predicate Device (ABSTACK30 – K090470)
Indications for Use	The device is indicated for fixation of prosthetic material to soft tissue in minimally invasive ventral and minimally invasive groin hernia repair procedures.	The device is intended for fixation of prosthetic material to soft tissue in minimally invasive and open surgical hernia repair procedures.
Target Anatomy	Abdominal wall (ventral & groin)	Abdominal wall (ventral & groin)
Surgical Procedures	Minimally Invasive hernia repair	Minimally Invasive and Open surgical hernia repair
Classification	OCW, 21 CFR 876.1500 GDW, 21 CFR 878.4750	OCW, 21 CFR 876.1500 GDW, 21 CFR 878.4750
Operating Principle	Push-button motorized firing mechanism to deploy tacks	Manual power grip squeeze to deploy tacks
Description	Straight configuration: stand-alone preloaded shaft with 30 tacks	Straight configuration: stand-alone preloaded shaft with 30 tacks
Sterilization	Ethylene Oxide (EO)	Ethylene Oxide (EO)
Biocompatibility	Evaluated per ISO 10993 series and FDA 2016 biocompatibility guidance	Evaluated per ISO 10993 series and FDA 2016 biocompatibility guidance
Tack Shape	Screw-like, with modified features	Screw-like
Tack Material	PGLA (Poly Glycolic and Lactic Acid)	PGLA (Poly Glycolic and Lactic Acid)
Tack Color	Violet & Green (25 tacks & 5 tacks respectively)	Violet (30 tacks)
Tack Length	7.0 mm	5.1 mm
Shaft Length	14 inches	14 inches
Shaft	304L Stainless Steel with laser etched logo and mesh manipulation/grip feature at distal end and	304L Stainless steel with laser etched logo and no mesh manipulation/grip feature

SUMMARY OF STUDIES:

Non-clinical performance data – The following studies have been performed to demonstrate substantial equivalence to the predicate device. When possible, applicable FDA-recognized standards were considered:

- Stability/Shelf-Life study for the single use devices
- Performance testing that includes:
  - Benchtop and *ex-vivo* testing
  - Reliability study performed to confirm the reliability of tack deployment and the functional integrity of the mesh manipulation grip feature at the distal end of the device
  - MaxTack™ *in-vivo* material strength study; MEDSD-2106 GLP Strength Loss Study of a Hernia Fixation Tack in a Rat Model
  - MaxTack™ *in-vitro* material strength correlation study
  - MaxTack™ *in-vitro* Mass Loss Study
- Usability study performed to fulfil the primary objectives supporting design change following the FDA's guidance as well as IEC 62366-1
- Biocompatibility testing of the green tacks and delivery system conducted in accordance with the FDA's 2020 guidance and ISO 10993-1 for their intended patient contact profile and historical data on the safety of the green dye (D&C Green No. 6) has been reviewed and presented.
- Software verification & validation activities completed following the FDA's guidance documents and IEC 62304
- Electrical safety testing per IEC 60601-1 and electromagnetic compatibility (EMC) testing per IEC 60601-1-2
- Cybersecurity Assessment following FDA's Guidance *"Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"* issued October 2, 2014.
- Following ASTM D4169 and EN ISO 11607-1, the protection of the product during shipping and storage was evaluated using packaging & product integrity testing.
- Ethylene oxide (EO) sterilization validation for the single use devices with a minimum Sterility Assurance Level (SAL) of 10^{-6}

Previously demonstrated compliance for the following aspects remain unimpacted:

- Biocompatibility evaluation of the violet tacks conducted for Predicate Device in accordance with the FDA's guidance and ISO 10993-1 for their intended patient contact profile.
- MR safety testing was performed on the Predicate device – K090470 and no change has been made to impact MR characteristics.
- Packaging stability of sterile barrier material was evaluated for representative material of sterile barrier, and requirements are met per EN ISO 11607-1:2020.

Clinical performance data – No clinical study is deemed necessary since the substantial equivalence has been sufficiently demonstrated through non-clinical studies.

CONCLUSION:

Based upon the supporting data summarized above, we concluded that the MaxTack™ Motorized Fixation Device, is as safe and effective as the legally marketed predicate device and does not raise any additional questions of safety and effectiveness than the predicate device.