



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Covidien LLC
Ms. Mary Mellows
Regulatory Affairs Product Manager
60 Middleton Avenue
North Haven, Connecticut 06473

July 17, 2015

Re: K151659

Trade/Device Name: ReliaTack™ Articulating Reloadable Fixation Device
with Deep Purchase Absorbable Tacks

Regulation Number: 21 CFR 878.4750

Regulation Name: Implantable Staple

Regulatory Class: Class II

Product Code: GDW

Dated: June 18, 2015

Received: June 18, 2015

Dear Ms. Mellows:

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" (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 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 yours,

Joshua C. Nipper -S

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

For

Enclosure

Indications for Use

510(k) Number (if known)

K151659

Device Name

ReliaTack™ Articulating Reloadable Fixation Device with Deep Purchase Absorbable Tacks

Indications for Use (Describe)

The device is intended for fixation of prosthetic material to soft tissue in various minimally invasive and 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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510(k) Summary of Safety and Effectiveness

Date Prepared:

June 18, 2015

Submitter:

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Contact:

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Name of Device:

Trade/Proprietary Name: ReliaTack™ Articulating Reloadable Fixation Device with Deep Purchase Absorbable Tacks
Common Name: Surgical Stapler with Implantable Staples
Classification Name: Staples, Implantable
a. Panel number and product code: 79 GDW
b. Regulation number: 21 CFR 878.4750

Predicate Device:

Trade/Proprietary Name: ReliaTack™ Articulating Reloadable Fixation Device with Standard Purchase Absorbable Tacks
Common Name: Surgical Stapler with Implantable Staples
Classification Name: Staples, Implantable
a. Panel number and product code: 79 GDW
b. Regulation number: 21 CFR 878.4750
510(k) Number: K140609
Manufacturer: Covidien

Device Description:

The ReliaTack™ Articulating Reloadable Fixation Device is a reloadable sterile, single use device for fixation of prosthetic material, such as mesh, to soft tissue. The tack is constructed of an absorbable synthetic polyester copolymer derived from lactic and glycolic acid and is dyed with D&C Violet No. 2. The device is offered as a stand-alone reloadable handle pre-packaged with:

K140609:

- Three, single use, ReliaTack™ reloads with 10 Standard Purchase (5.1mm) absorbable (PGLA) tacks

Or

Proposed

- One, single use, ReliaTack™ reload with 5 Deep Purchase (7.0mm) absorbable (PGLA) tacks & three, single use, ReliaTack™ reloads with 8 Deep Purchase (7.0mm) absorbable (PGLA) tacks

Single use reloads can be packaged separately in the following configurations:

K140609:

- one ReliaTack™ reload with 5 Standard Purchase (5.1mm) absorbable (PGLA) tacks
- one ReliaTack™ reload with 10 Standard Purchase (5.1mm) absorbable (PGLA) tacks

Or

Proposed

- one ReliaTack™ reload with 5 Deep Purchase (7.0mm) absorbable (PGLA) tacks
- one ReliaTack™ reload with 8 Deep Purchase (7.0mm) absorbable (PGLA) tacks

Intended Use:

The ReliaTack™ Articulating Reloadable Fixation Device with Deep Purchase Absorbable Tacks is indicated for fixation of prosthetic material to soft tissue in various minimally invasive and open surgical procedures such as hernia repair.

Technological and Performance Characteristics:

The ReliaTack™ Articulating Reloadable Fixation Device with Deep Purchase Absorbable Tacks is substantially equivalent to the predicate ReliaTack™ Articulating Reloadable Fixation Device with Standard Purchase Absorbable Tacks in regard to the fixation technologies employed.

Qualitative and quantitative data were obtained and used to compare the ReliaTack™ Articulating Reloadable Fixation Device with Deep Purchase Absorbable Tacks to the predicate ReliaTack™ Articulating Reloadable Fixation Device with Standard Purchase Absorbable Tacks (K140609).

All aspects were found to be identical, with the exception of the following characteristics:

1. The length of the ReliaTack™ Absorbable Tack:
 - Predicate (K140609) ReliaTack™ Standard Purchase Absorbable Tacks = 5.1mm
 - Proposed ReliaTack™ Deep Purchase Absorbable Tacks = 7.0mm
2. The length of the ReliaTack™ Single Use Reload
 - Predicate (K140609) ReliaTack™ Standard Purchase 5 Tack Reload = 2.062 in.
 - Predicate (K140609) ReliaTack™ Standard Purchase 10 Tack Reload = 3.102 in.
 - Proposed ReliaTack™ Deep Purchase 5 Tack Reload = 2.495 in.
 - Proposed ReliaTack™ Deep Purchase 8 Tack Reload = 3.348 in.

The design differences were found to have no impact on safety or performance. This was established through applicable design verification activities that showed continued conformance to applicable technical design specifications and performance requirements, applicable medical device performance standards, and other nonclinical testing.

Tests performed to evaluate and compare technological and performance characteristics:

1. Bench tests using simulated tissue medium and mesh were performed to evaluate the following technological and performance characteristics in order to show the equivalence of the proposed device to the predicate device (K140609):
 - Trigger firing force
 - Joint strength (hyper-articulation and de-articulation)
 - Insertion/removal force
 - Load/unload force
 - Media shear force
 - Tack shear strength loss
 - Tack mass loss
2. *Ex vivo* tests using porcine tissue were performed to evaluate the following performance characteristics:
 - Torque required to drive tacks into tissue
3. Usability Tests
4. Biocompatibility tests in accordance with ISO Standard 10993-1 were performed to confirm that all components of the ReliaTack™ Articulating Reloadable Fixation Device

with Deep Purchase Absorbable Tacks are comprised of materials that are in accordance with ISO Standard 10993-1 for their intended patient contact profile.

This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Conclusion:

Through the comparison of technological and performance characteristics and the results of evaluation testing, the ReliaTack™ Articulating Reloadable Fixation Device with Deep Purchase Absorbable Tacks was found to be substantially equivalent to the predicate device, ReliaTack™ Articulating Reloadable Fixation Device with Standard Purchase Absorbable Tacks (K140609).