APR 0 9 2014

510(k) Summary

This 510(k) summary information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.98.

Submitter Information

Name:	Covidien llc
Address:	60 Middletown Avenue North Haven, CT 06473
Establishment Registration:	1219930
Name of contact person:	Clare Santulli Regulatory Affairs Manager Covidien 60 Middletown Avenue North Haven, CT 06473 USA Phone: (203) 492-7635
Date prepared:	March 7, 2014
Trade or proprietary name:	ReliaTack™ Articulating Reloadable Fixation Device with Standard Purchase Absorbable Tacks
Common or usual name: **Classification name:** **Classification panel:**	Surgical Stapler with Implantable Staple Staple, Implantable General and Plastic Surgery (79)
Regulation:	21 CFR 878.3300
Product Code:	GDW
Legally marketed devices to which equivalence is claimed:	AbsorbaTack™ Absorbale Fixation Device (K123109)
Reason for 510(k) submission:	To obtain market clearance for the ReliaTack™ Articulating Reloadable Fixation Device with Standard Purchase

Absorbable Tacks

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 prepackaged with three 10 standard purchase tack single use reloads. The reloads and handle that are packaged together are designed to be used together.

The ReliaTack™ Articulating Reloadable Fixation Device can accommodate

- 10 standard purchase tack reloads with 5.1mm long absorbable PGLA tacks
- 5 standard purchase tack reloads with 5.1mm long absorbable PGLA tacks

Intended use of the device:

The device is intended for fixation of prosthetic material to soft tissue in various minimally invasive and open surgical procedures such as hernia repair.

Summary comparing the technological characteristics of the subject and predicate devices:

The ReliaTack™ Articulating Reloadable Fixation Device with Standard Purchase Absorbable Tacks is substantially equivalent to the predicate devices with regard to Trigger firing force, media shear force and shaft side load.

Materials:

All components of ReliaTack™ Articulating Reloadable Fixation Device with Standard Purchase Absorbable Tacks are comprised of materials which are in accordance with ISO Standard 10993-1.

Performance Data:

Bench performance evaluations were completed to show ReliaTack™ Articulating Reloadable Fixation Device with Standard Purchase Absorbable Tacks is substantially equivalent to the predicate device and perform as intended.

The tests performed to show substantial equivalence of the ReliaTack™ Articulating Reloadable Fixation Device with Standard Purchase Absorbable Tacks to the predicate device are as follows:

- *in vitro*
  - Trigger Firing Force
  - Shaft Side Load
  - Media Shear Force
  - Safety Lock-Out Test
- *in vivo*
  - Tissue trauma (patient)
  - Tissue trauma (user)
- Biocompatibility

Conclusion:

The results of the tests performed demonstrate that the subject device, ReliaTack™ Articulating Reloadable Fixation Device with Standard Purchase Absorbable Tacks is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 9, 2014

Covidien LLC
Ms. Clare Santulli
Regulatory Affairs Manager
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K140609
Trade/Device Name: ReliaTack™ Articulating Reloadable Fixation Device with Standard Purchase Absorbable Tacks
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: March 7, 2014
Received: March 10, 2014

Dear Ms. Santulli:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting 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)*
K140609

Device Name
ReliaTack™ Articulating Reloadable Fixation Device with Standard 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Peter L. Hudson -S
2014.04.08 15:44:55 -04'00'

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