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JUL 1 2 2013

510(k) Summary

Applicant Information

Applicant Name:	Rotation Medical, Inc.
Applicant Address:	15350 25th Avenue North, Suite 100 Plymouth, MN 55447
Telephone:	763-746-7521
Fax:	763-746-7501
Contact Person:	Gail Schroeder Director, Quality Assurance and Operations
Date Prepared:	May 31, 2013

Name of Device

Device Common Name:	Absorbable Soft Tissue Staple
Device Trade Name:	Rotation Medical Soft Tissue Staple (RMST Staple)
Device Classification Name:	Staple, Implantable 878.4750 Class II GDW

Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device(s):	Ethicon SecurestrapTM 5mm Absorbable Strap Fixation Device, K093845; Ethicon, Inc.

Description of the Device

RMST Staple is an absorbable polymer strap with cleat tips. RMST Staple is composed of absorbable synthetic polyester derived from lactic acid and dyed with D&C Violet #2. The RMST Staple is used in conjunction with an orthopedic manual staple driver from Rotation Medical. (Note: Rotation Medical's orthopedic manual staple driver is a Class I exempt device pursuant to 21 CFR 888.4540 and is not the subject of this submission).

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Intended Use

The RMST Staple is intended for fixation of prosthetic material to soft tissues in various minimally invasive and open surgical procedures, such as the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Summary/Comparison of Technical Characteristics

RMST Staple and the predicate device have similar indications for use, technological characteristics, and material composition. Both devices are comprised of a polymer strap with barbed ends which engage in soft tissue. RMST Staple and the currently marketed Ethicon Securestrap (predicate device) are both indicated for the fixation of prosthetic material to soft tissues in various minimally invasive and open surgical procedures. Both devices are composed of similar absorbable synthetic polyester and contain the same D&C Violet #2 dye.

RMST Staple has been evaluated in a number of in vitro and in vivo tests to assess its safety/biocompatibility, including: tensile strength, retention strength (pull-out), cytotoxicity, sensitization, intercutaneous reactivity, acute systemix toxicity, genotoxicity, pyrogenicity, muscle implantation, subchronic toxicity, and hemolysis. RMST Staple and its predicate have been characterized for general physical properties including size, surface area, weight, and strength retention to demonstrate substantial equivalence.

Conclusion

The device passed all applicable FDA Blue Book Memorandum G95-1 and ISO 10993-1 testing for the biological evaluation of medical devices. The results of the in vitro product characterization studies, bench testing and in vitro and in vivo biocompatibility studies, as well as the animal efficacy study demonstrate that the RMST Staple is safe and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Rotation Medical, Inc.
% Ms. Gail Schroeder
Director, Quality Assurance and Operations
15350 25th Avenue North, Suite 100
Plymouth, Minnesota 55447

July 12, 2013

Re: K131637
Trade/Device Name: Rotation Medical Soft Tissue Staple (RMST Staple)
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: May 31, 2013
Received: June 04, 2013

Dear Ms. Schroeder:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131637

Device Name: Rotation Medical Soft Tissue Staple (RMST Staple)

Indications for Use:

The RMST Staple is intended for fixation of prosthetic material to soft tissues in various minimally invasive and open surgical procedures, such as the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131637