K103052
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510(k) Summary of Safety and Effectiveness

NOV 10 2010

SUBMITTER:	Surgical Devices, a global business unit of Tyco Healthcare Group LP (d/b/a Covidien) 60 Middletown Avenue North Haven, CT 06473
CONTACT PERSON:	Jennifer Brennan Manager, Regulatory Affairs Tel. No.: (203) 492-5346
DATE PREPARED:	September 30, 2010
TRADE/PROPRIETARY NAME:	V-Loc™ Nonabsorbable Wound Closure Device
COMMON/USUAL NAME:	Synthetic Nonabsorbable Suture
CLASSIFICATION NAME:	Nonabsorbable poly(ethylene terephthalate) surgical suture
PREDICATE DEVICE(S):	Syneture™ Novafil™ Synthetic Absorbable Suture (K990952) V-Loc™ 180 Absorbable Wound Closure Device (K090348)
DEVICE DESCRIPTION:	The V-Loc™ Nonabsorbable Wound Closure Device is a polybutester suture prepared from a copolymer of butylene terephthalate and polytetramethlyene ether glycol. Each device has unidirectional barbs along the axis of the monofilament. The V-Loc™ Nonabsorbable Wound Closure Device will be offered both Undyed (clear) and Dyed with [Phthalocyaninato(2-)] copper (21 CFR 74.3045) at a level not exceeding 0.5% by weight of the suture in sizes USP (EP) 3-0 (Metric 3), 2-0 (Metric 3.5), 0 (Metric 4) and 1 (Metric 4.5). They will be supplied in pre-cut lengths affixed to various needle types.
INDICATIONS:	V-Loc™ Nonabsorbable Wound Closure Devices are indicated for soft tissue approximation.
TECHNOLOGICAL CHARACTERISTICS:	V-Loc™ Nonabsorbable Wound Closure Device is substantially equivalent to the predicate devices with regards to use in soft tissue approximation.
MATERIALS:	All components of the V-Loc™ Nonabsorbable Wound Closure Device are comprised of materials that are in compliance with ISO standard 10993-1.
PERFORMANCE DATA:	Performance testing was conducted to verify that the V-Loc™ Nonabsorbable Wound Closure Device is safe and effective and performs as intended. The following is a description of tests performed and associated conclusions:

- **In-vitro performance evaluation (bench testing)**
  - Needle Attachment meets USP/EP specification.
  - Diameter (non-barbed suture) – Maximum Overage of USP/EP specification as stated in the Instructions for Use.
  - Tensile Strength (T=0 straight pull evaluation)– Pass
  - Barb Holding Strength (T=0 simulated barb holding of felt medium) - Pass
- **In-vivo performance evaluation**
  - **Product safety and efficacy in porcine model**
    Chronic 21 day study with biomechanical testing at T=3, T=7, and T=21 days to compare the burst pressure of the sutured incision of the control (predicate V-Loc™ 180 Absorbable Wound Closure Device) and the test (V-Loc™).
    Results: No statistical differences in burst pressure between the barbed control (V-Loc™ 180) and test device (V-Loc™ Nonabsorbable).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Covidien LLC
% Ms. Jennifer Brennan
Manager, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

NOV 10 2010

Re: K103052
Trade/Device Name: V-Loc™ Nonabsorbable Wound Closure Device
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT
Dated: October 12, 2010
Received: October 14, 2010

Dear Ms. Brennan:

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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K103052

NOV 10 2010

Device Name: **V-Loc™ Nonabsorbable Wound Closure Device**

Indications For Use:

V-Loc™ Nonabsorbable Wound Closure Device is indicated for soft tissue approximation.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103052