K093408
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5. 510(k) SUMMARY:

510(K) Summary of Safety and Effectiveness:

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:	Nishith Desai Associate Manager, Regulatory Affairs Phone: (203) 492-6339 Fax: (203) 492-5029
	NOV 12 2009
DATE PREPARED:	August 24, 2009
TRADE/PROPRIETARY NAME:	V-Loc™ 180 Absorbable Wound Closure Device
COMMON/USUAL NAME:	Synthetic Absorbable Suture
CLASSIFICATION NAME:	Polyglycolic Acid Absorbable Surgical Suture
PREDICATE DEVICE(S):	1) V-Loc™ 180 Absorbable Wound closure Device, K091807 2) Syneture™ Maxon™ Synthetic Absorbable Suture, K990951 3) Quill™ Self-Retaining (SRS) comprised of PDO (Polydioxoanone), K080985
DEVICE DESCRIPTION:	The V-Loc™ 180 absorbable wound closure device (Size 4-0) is prepared from a copolymer of glycolic acid and trimethylene carbonate. The absorbable wound closure device is available clear or green. The device is sterile, inert, noncollagenous and nonantigenic.
INTENDED USE:	V-Loc™ 180 absorbable wound closure devices are indicated for soft tissue approximation where use of an absorbable suture is appropriate.
TECHNOLOGICAL CHARACTERISTICS:	V-Loc™ 180 absorbable wound closure device (Size 4-0) is identical to the predicate device.
MATERIALS:	V-Loc™ 180 absorbable wound closure device (Size 4-0) is comprised of materials which have been evaluated in accordance with ISO 10993-1: 2003, Biological Evaluation of medical devices – Part I Evaluation and Testing.
PERFORMANCE DATA:	Performance testing (in vitro and in vivo) was conducted to verify that the V-Loc™ 180 Absorbable Wound Closure Device (Size 4-0) is safe and effective and performs as intended.

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

Surgical Devices
Tyco Healthcare Group LP
(d/b/a Covidien)
% Mr. Nishith Desai
Associate Manager, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

NOV 12 2009

Re: K093408
Trade/Device Name: V-Loc™ 180 Absorbable Wound Closure Device
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/L-lactide) surgical suture
Regulatory Class: Class II
Product Code: GAM
Dated: October 30, 2009
Received: November 2, 2009

Dear Mr. Desai:

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.

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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

for

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

Enclosure

4. INDICATIONS FOR USE STATEMENT:

510(k) Number (if known): K093408

Device Names: V-Loc™ 180 Absorbable Wound Closure Device

Indications For Use: V-Loc™ 180 absorbable wound closure devices are indicated for soft tissue approximation where use of an absorbable suture is appropriate.

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krane for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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