MAR 2 6 2009

K062662 Page 1 of 1

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:	Renee Borgesano Manager, Regulatory Affairs Tel. No.: (203) 492-6060
DATE PREPARED:	September 11, 2008
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):	Syneture™ Maxon™ Synthetic Absorbable Suture (K990951) Quill TM Synthetic Absorbable Barbed Suture (K042075)
DEVICE DESCRIPTION:	The V-Loc™ 180 Absorbable Wound Closure Device is a suture prepared from a copolymer of glycolic acid and trimethylene carbonate. Each device has unidirectional barbs along the axis of the monofilament. The V-Loc™ 180 Absorbable Wound Closure Device will be offered dyed with D&C Green No. 6 (21 CFR 74.3206) or clear (undyed) in sizes USP (EP) 2-0 (Metric 3), 0 (Metric 3.5) and 1 (Metric 4). They will be supplied in pre-cut lengths affixed to various needle types.
INDICATIONS:	V-Loc™ 180 Absorbable Wound Closure Device is indicated for soft tissue approximation where use of an absorbable suture is appropriate.
TECHNOLOGICAL CHARACTERISTICS:	V-Loc™ 180 Absorbable 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™ 180 Absorbable 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™ 180 Absorbable Wound Closure Device is safe and effective and performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2009

Covidien
% Ms. Renee Borgesano
Manager, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K082662
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: II
Product Code: GAM
Dated: February 26, 2009
Received: March 4, 2009

Dear Ms. Borgesano:

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 Fed-ral 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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications For Use

510(k) Number (if known): K082662

Device Name: **V-Loc™ 180 Absorbable Wound Closure Device**

Indications For Use:

V-Loc™ 180 Absorbable Wound Closure Device is indicated for soft tissue approximation where use of an absorbable suture is appropriate.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (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 MXM 3/26/2009

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082662