

MAR 26 2009

K042602 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™ 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.



MAR 26 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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 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 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.

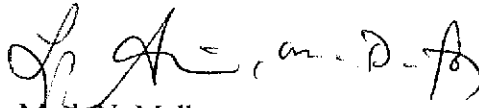
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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): 2082662

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 Krone for MXM 3/26/2009

(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) Number 2082662