5. 510(k) SUMMARY:

APR 22 2009

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:	Jennifer Brennan Manager, Regulatory Affairs Phone: (203) 492-5346 Fax: (203) 492-5029
DATE PREPARED:	April 7, 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):	K082662 - V-loc™ 180 Absorbable Wound Device
DEVICE DESCRIPTION:	The V-Loc™ 180 absorbable wound closure device 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 is identical to the predicate device.
MATERIALS:	V-Loc™ 180 absorbable wound closure device are 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 is not applicable as there has been no change to the V-Loc™ 180 absorbable wound closure device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Surgical Devices, Tyco HealthCare Group, LP
% Ms. Jennifer Brennan
Manger, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

APR 22 2009

Re: K091087
Trade/Device Name: V-loc™ Absorbable Wound Closure Device
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly (glycolide lactide) surgical suture
Regulatory Class: II
Product Code: GAM
Dated: April 7 2009
Received: April 15, 2009

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 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

for

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

Enclosure

4. INDICATIONS FOR USE STATEMENT:

510(k) Number (if known): K091087

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 Krause for MKM

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

510(k) Number K091087