510(k) Summary of Safety and Effectiveness

JUN - 3 2011

SUBMITTER:	Covidien llc (formerly registered as Tyco Healthcare, LP) 60 Middletown Avenue North Haven, CT 06473 Tel. No.: (203) 492-5000
CONTACT PERSON:	Robert Zott Program Director, Regulatory Affairs 60 Middletown Avenue North Haven, CT 06473 USA Phone: (203) 492-5493 Fax: (203) 492-6602
DATE PREPARED:	May 17, 2011
TRADE/PROPRIETARY NAME:	V-Loc™ 180 Absorbable Reload V-Loc™ PBT Non-Absorbable Reload Endo Stitch™ Endoscopic Suturing Device SILS™ Stitch Endoscopic Suturing Device
COMMON/USUAL NAME:	Synthetic Absorbable and Nonabsorbable Sutures Endoscopic Suturing Devices
CLASSIFICATION NAME:	V-Loc™ 180 Absorbable Reload: Absorbable poly(glycolide/l-lactide) surgical suture 21 CFR 878.4493 V-Loc™ PBT Non-Absorbable Reload: Nonabsorbable poly(ethylene terephthalate) surgical suture 21 CFR 878.5000 Endo Stitch™ Endoscopic Suturing Device Endoscopic Tissue Approximation Device 21 CFR 876.1500 SILS™ Stitch Endoscopic Suturing Device Endoscopic Tissue Approximation Device 21 CFR 876.1500
PREDICATE DEVICE(S):	V-Loc™ 180 Absorbable Wound Closure Device, Covidien (K091087 and K082662) V-Loc™ Non-Absorbable Wound Closure Device (PBT), Covidien (K103052) Endo Stitch™ Endoscopic Suturing Device, Covidien (K934738) SILS™ Stitch, Covidien (K090419)

	USSC Non-absorbable Sutures, Covidien (K955747)
DEVICE DESCRIPTION:	Absorbable and non-absorbable synthetic suture reloads for endoscopic suturing devices
INTENDED USE:	V-Loc™ 180 Absorbable Reload: The V-Loc™ 180 absorbable reloads are intended for use with the Endo Stitch™ suturing device and SILS™ Stitch suturing device. The Endo Stitch™ suturing device and SILS™ Stitch suturing device, when used with the reloads, have application in endoscopic surgery for the placement of running stitches in soft tissue. The V-Loc™ 180 absorbable reloads are indicated for soft tissue approximation where use of an absorbable suture is appropriate. V-Loc™ PBT Non-Absorbable Reload: The V-Loc™ PBT non-absorbable reloads are intended for use with the Endo Stitch™ suturing device and SILS™ Stitch suturing device. The Endo Stitch™ suturing device and SILS™ Stitch suturing device, when used with the reloads, have application in endoscopic surgery for the placement of running stitches in soft tissue. The V-Loc™ PBT non-absorbable reloads are indicated for soft tissue approximation.
TECHNOLOGICAL CHARACTERISTICS:	The implantable portions of the V-Loc™ Reloads are identical to the predicate V-Loc™ Wound Closure Devices in terms of indications, labeling, materials, performance, and technology. The only differences are the manner in which they are attached to their respective needles and the lengths in which they are supplied. The modifications include the addition of a braided leader and ferrule in order to connect the V-Loc™ suture to a needle specifically designed to be captured and passed between the jaws of an endoscopic suturing device. The needles and materials used for the leader and ferrule have been previously-cleared in the cited predicate devices. The Endo Stitch™ and SILS Stitch™ Endoscopic Suturing Devices have not been changed.
MATERIALS:	All component materials of the V-Loc™ 180 Absorbable Reload and the V-Loc™ PBT Non-Absorbable Reload have been evaluated in accordance with ISO 10993-1: Biological Evaluation of Medical Devices, according to their intended use. These materials have also been previously cleared in predicate devices for the identical intended use.
PERFORMANCE DATA:	Performance testing has been performed in support of the intended use of these devices. This testing verifies that the V-Loc™ 180 Absorbable Reload and the V-Loc™ PBT Non-Absorbable Reload are substantially equivalent to the predicate devices. The following performance standards were used:

- USP Monograph for Sutures (33, NF 28, 2010) – Physical Test <861> Diameter
- USP Monograph for Sutures (33, NF 28, 2010) – Physical Test <871> Needle Attachment

The subject devices were evaluated in the following bench top and in vivo tests:

- Needle Attachment
- Insertion / Removal Forces through Port Cannula
- Tensile Strength
- Barbed Suture Holding Strength
- Tissue Passage

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Covidien
% Mr. Robert Zott
Program Director, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

JUN - 3 2011

Re: K111442
Trade/Device Name: V-Loc™ 180 Absorbable Reload, V-Loc™ PBT Non-Absorbable Reload
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/L- lactide) surgical suture
Regulatory Class: II
Product Code: GAM, GAT, OCW
Dated: May 17, 2011
Received: May 24, 2011

Dear Mr. Zott:

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):

Device Name: V-Loc™ 180 Absorbable Reload

Indications for Use:

The V-Loc™ 180 absorbable reloads are intended for use with the Endo Stitch™ suturing device and SILS™ Stitch suturing device. The Endo Stitch™ suturing device and SILS™ Stitch suturing device, when used with the reloads, have application in endoscopic surgery for the placement of running stitches in soft tissue. The V-Loc™ 180 absorbable reloads are indicated for soft tissue approximation where use of an absorbable suture is appropriate.

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)

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

510(k) Number K 111442

Indications for Use

510(k) Number (if known):

Device Name: V-Loc™ PBT Non-Absorbable Reload

Indications for Use:

The V-Loc™ PBT non-absorbable reloads are intended for use with the Endo Stitch™ suturing device and SILS™ Stitch suturing device. The Endo Stitch™ suturing device and SILS™ Stitch suturing device, when used with the reloads, have application in endoscopic surgery for the placement of running stitches in soft tissue. The V-Loc™ PBT non-absorbable reloads are 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 Krum for MKM

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

510(k) Number K111442