SEP 2 8 2007

510(k) Summary of Safety and Effectiveness

SUBMITTER:	United States Surgical, a division of Tyco Healthcare Group LP 150 Glover Avenue Norwalk, CT 06856 Tel. No.: (203) 845-1000
CONTACT PERSON:	Daniel Campion Associate II, Regulatory Affairs
DATE PREPARED:	July 10, 2007
TRADE/PROPRIETARY NAME:	Syneture™ Absorbable Tack and Applicator
COMMON/USUAL NAME:	Absorbable Tack and Applicator
CLASSIFICATION NAME:	Implantable Staple
PREDICATE DEVICE(S):	AbsorbaTack™ and Applicator (K071061) E-Z Tac™ (K961585)
DEVICE DESCRIPTION:	The Syneture™ Absorbable Tack and Applicator are sterile single use devices for the fixation of prosthetic material, such as hernia mesh, onto soft tissue. The Absorbable Tack is formed from synthetic polyester derived from a lactic acid and glycolic acid copolymer. The Applicator is offered with a range of 5 to 20 tacks.
INTENDED USE:	The Syneture™ Absorbable Tack and Applicator are intended for fixation of prosthetic material to soft tissue in various minimally invasive and open general surgical procedures, such as hernia repair.
TECHNOLOGICAL CHARACTERISTICS:	The Syneture™ Absorbable Tack and Applicator is identical to the predicate device in terms of intended use and mode of operation.
PERFORMANCE DATA:	Performance testing was conducted to verify that the Syneture™ Absorbable Tack and Applicator 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

United States Surgical, a Division of Tyco Healthcare Group, LP
% Mr. Daniel Campion
Regulatory Affairs Associate II
150 Glover Avenue
Norwalk, Connecticut 06856

SEP 2 8 2007

Re: K071920
Trade/Device Name: Syneture™ Absorbable Tack and Applicator
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: September 18, 2007
Received: September 19, 2007

Dear Mr. Campion:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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
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): _____

Device Name: **Syneture™ Absorbable Tack and Applicator**

Indications For Use:

The Syneture™ Absorbable Tack and Applicator are intended for fixation of prosthetic material to soft tissue in various minimally invasive and open general surgical procedures, such as hernia repair.

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 General, Restorative, and Neurological Devices

510(k) Number K071920