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

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

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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**

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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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2007

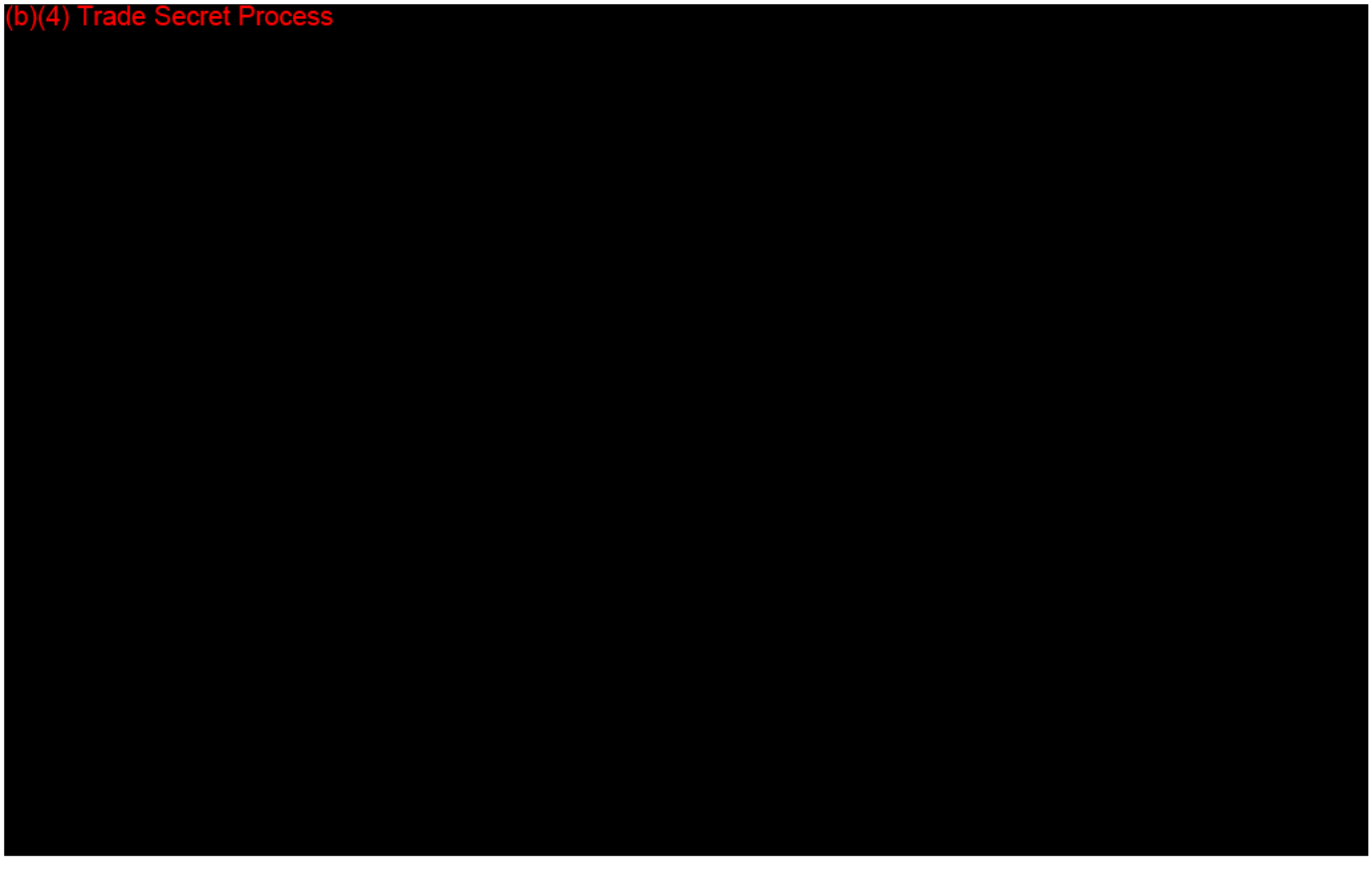
United States Surgical, a Division
of Tyco Healthcare Group, LP
% Mr. Daniel Campion
Associate II, Regulatory Affairs
150 Glover Avenue
Norwalk, Connecticut 06850

Re: K071920
Trade Name: Syneture™ Absorbable Tack and Applicator
Received: July 12, 2007

Dear Mr. Campion:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following:

(b)(4) Trade Secret Process



When using a standard to demonstrate equivalence, providing a declaration of conformity or a statement that the device will comply prior to marketing, may be provided in lieu of data. Please refer to our document, titled Use of Standards in Substantial Equivalence Determinations located at http://www.fda.gov/cdrh/ode/guidance/1131.pdf for additional guidance.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/cdrh/modact/leastburdensome.html

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Tajanay Ki at (240) 276-3625. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark Melkerson

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

SEP 12 2007

United States Surgical, a Division
of Tyco Healthcare Group, LP
% Mr. Daniel Campion
Associate II, Regulatory Affairs
150 Glover Avenue
Norwalk, Connecticut 06850

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Received: July 12, 2007

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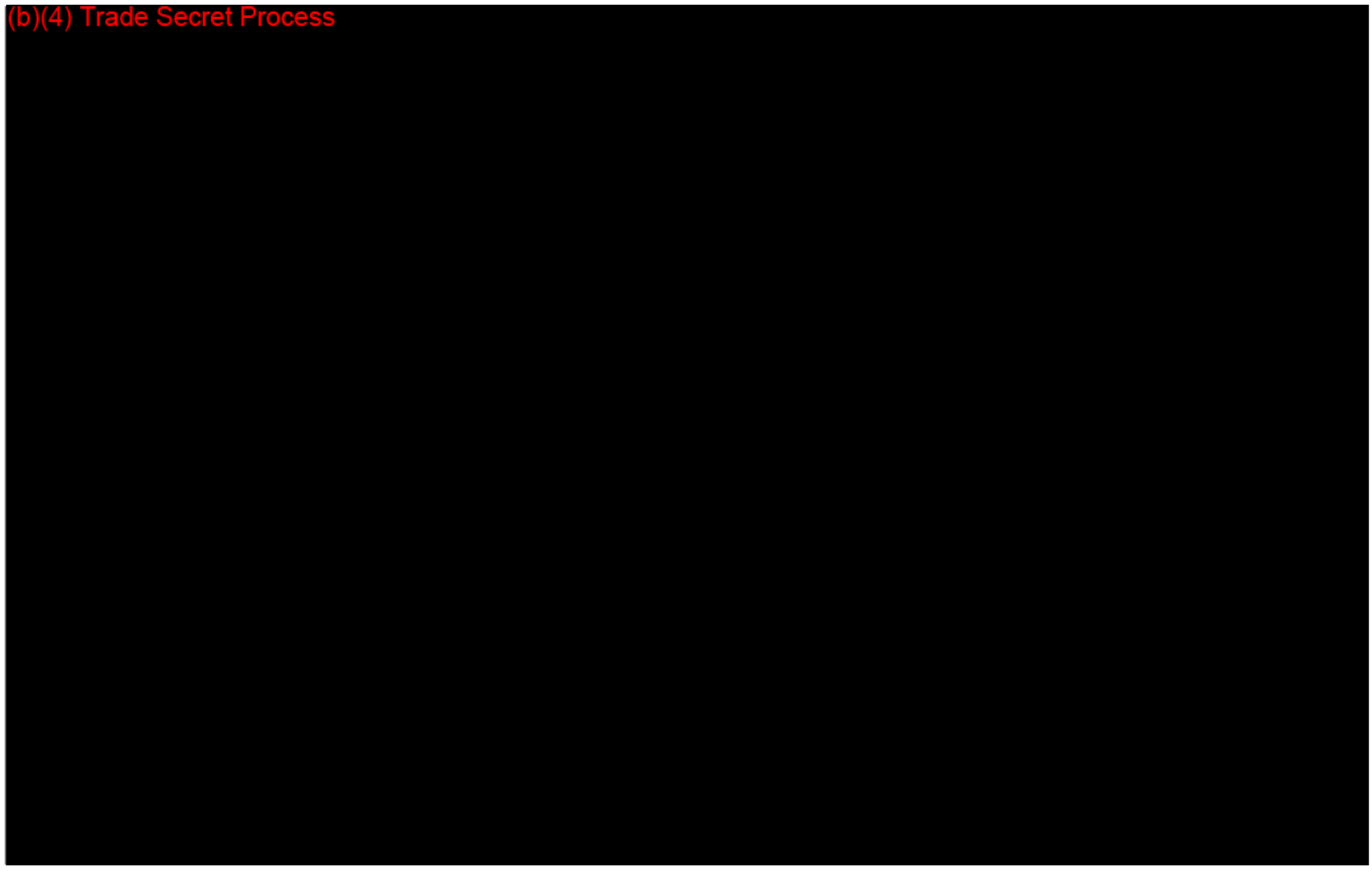

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Sincerely yours,

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

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-410		9/11/03						
HFZ-410		9/11/03						
HFZ-410		9/11/03						

★ U.S. GOVERNMENT PRINTING OFFICE 1991-519-771

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 (DGRND/PRSB)
D.O.
f/t:TRN:tlm:9-11-07

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

July 13, 2007

UNITED STATES SURGICAL, A DIVISION
150 GLOVER AVE.
NORWALK, CT 06856
ATTN: DANIEL CAMPION

510(k) Number: K071920
Received: 12-JUL-2007
Product: AUTOSUTURE ABSORBABLE TACK AND APPLICATOR

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k))Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k). 3)Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

July 12, 2007

UNITED STATES SURGICAL, A DIVISION
150 GLOVER AVE.
NORWALK, CT 06856
ATTN: DANIEL CAMPION

510(k) Number: K071920
Received: 12-JUL-2007
User Fee ID Number: 6031386
Product: AUTOSUTURE ABSORBABLE TACK AND

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail	By Private Courier(e.g.,Fed Ex, UPS, etc.)
Food and Drug Administration P.O. Box 956733 St. Louis, MO 63195-6733.	U.S. Bank 956733 1005 Convention Plaza St. Louis, MO 63101 (314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (240)276-4025 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/oc/mdufma.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-fee number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Christina Zeender at Christina.Zeender@fda.hhs.gov. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Office of Device Evaluation
Center for Devices and
Radiological Health

K071920

510(k) Premarket Notification
for
Syneture™ Absorbable Tack and Applicator

K4/

Table of Contents

Note: CDRH Guidance for Industry and FDA Staff, "Format for Traditional and Abbreviated 510(k)s", dated August 12, 2005, has been used in compiling this submission.

Screening Checklist
For All Premarket Notification [510(k)] Submissions

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

☐ Special 510(k) – Do Sections 1 and 2

☐ Abbreviated 510(k) – Do Sections 1, 3 and 4

☒ Traditional 510(k) or no identification provided – Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present [Page(s)]	**Missing or Inadequate**
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	16-17	
Table of Contents.	2	
Truthful and Accurate Statement.	22	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	10-12 & 16	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	12 & 16	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	26, A1	
Statement of Indications for Use that is on a separate page in the premarket submission.	19	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	24-26	
510(k) Summary or 510(k) Statement.	21	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	23-24, A2	
Identification of legally marketed predicate device.*	24	
Compliance with performance standards.* [See Section 514 of the Act and 21 CFR 807.87 (d).]	NA	NA
Class III Certification and Summary.**	NA	NA
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study.* [See 21 CFR 807.87 (i)]	NA	NA
510(k) Kit Certification***	NA	NA

* May not be applicable for Special 510(k)s.
** Required for Class III devices, only.
*** See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present [Page(s)]	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	N/A	N/A
A description of the modified device and, a comparison to the sponsor's predicate device.	N/A	N/A
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	N/A	N/A
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.	N/A	N/A
A Design Control Activities Summary that includes the following elements (a-c):	N/A	N/A
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	N/A	N/A
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	N/A	N/A
c. A Declaration of Conformity with design controls that includes the following statements:	N/A	N/A
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.	N/A	N/A
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	N/A	N/A

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present [Page(s)]	**Inadequate or Missing**
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)	NA	NA
For a submission, which relies on a recognized standard, a declaration of conformity.	NA	NA
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.	NA	NA
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.	NA	NA
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.	NA	NA
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.	NA	NA

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present [Page(s)]	**Inadequate or Missing**
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation	27	
b) Sterilization and expiration dating information:	26-27	
i) sterilization process	26	
ii) validation method of sterilization process	27	
iii) SAL	27	
iv) packaging	27	
v) specify pyrogen free	27	
vi) ETO residues	27	
vii) radiation dose	27	
viii) Traditional Method or Non-Traditional Method	27	
c) Software Documentation	27	

1. Medical Device User Fee Cover Sheet (Form FDA 3601)

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010 See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade Secret
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

TYCO HEALTHCARE LLP
150 GLOVER AVENUE
Norwalk CT 06856
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)(4)

2. CONTACT NAME
Daniel Campion

2.1 E-MAIL ADDRESS
daniel.campion@tycohealthcare.com

2.2 TELEPHONE NUMBER (include Area code)
203-492-6339

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
null-null

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/cdrh/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) 19-Jun-2007

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

2. CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
6/27/2007	(b)(4) Trade	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
United States Surgical, a Division of Tyco Healthcare Group, LP	1219161		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	(203) 492-6339		
Street Address	FAX Number *(including area code)*		
150 Glover Avenue	(203) 492-5029		
City	State / Province	ZIP/Postal Code	Country
Norwalk	CT	06850	USA
Contact Name			
Daniel Campion			
Contact Title	Contact E-mail Address		
Associate II, Regulatory Affairs	daniel.campion@tycohealthcare.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	( )		
Street Address	FAX Number *(including area code)*		
	( )		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
ntact Title	Contact E-mail Address		

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify)*:
  Change in Polymer Material used to form the Tack.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GDW	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

ormation on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K071061	1	AbsorbaTack™ and Applicator	1	United States Surgical, a Division of Tyco Healthcare Group, LP
2	K961585	2	E-Z Tac™ Soft Tissue Reattachment System	2	United States Surgical, a Division of Tyco Healthcare Group, LP
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Implantable Staple

	Trade or Proprietary or Model Name for This Device		Model Number
1	autosuture™ Absorbable Tack and Applicator	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K821251	2 K900122	3 K961585	4 K963999	5 K071061	6 K060494
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☒ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
GDW	878.4750	☐ Class I ☒ Class II
Classification Panel: General and Plastic Surgery		☐ Class III ☐ Unclassified

Indications *(from labeling)*

e Absorbable Tack and Applicator are indicated for fixation of prosthetic material to soft tissue in various minamally invasive and open general surgical procedures, such as hernia repair.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number: 1219161	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name: United States Surgical, a Division of Tyco Healthcare Group, LP		Establishment Registration Number: 1219161	
Division Name *(if applicable)*		Phone Number *(including area code)*: (203) 492-6339	
Street Address: 150 Glover Avenue		FAX Number *(including area code)*: (203) 492-5029	
City: Norwalk	State / Province: CT	ZIP/Postal Code: 06850	Country: USA
Contact Name: Daniel Campion	Contact Title: Associate II, Regulatory Affairs	Contact E-mail Address: daniel.campion@tycohealthcare.com	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*: ( )	
Street Address		FAX Number *(including area code)*: ( )	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*: ( )	
Street Address		FAX Number *(including area code)*: ( )	
City	State / Province	ZIP/Postal Code	Country
ntact Name	Contact Title	Contact E-mail Address	

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1					
	Standards No.	Standards Organization	Standards Title	Version	Date
2					
	Standards No.	Standards Organization	Standards Title	Version	Date
3					
	Standards No.	Standards Organization	Standards Title	Version	Date
4					
	Standards No.	Standards Organization	Standards Title	Version	Date
	Standards No.	Standards Organization	Standards Title	Version	Date
6					
	Standards No.	Standards Organization	Standards Title	Version	Date
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

...t agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

3. 510(k) Cover Letter

July 10, 2007

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: Traditional 510(k): Device Modification (21 CFR 807.90(e))
• Syneture™ Absorbable Tack and Applicator

Dear Madam or Sir:

United States Surgical is submitting this **Traditional 510(k): Device Modification** in duplicate to report the change in absorbable polymer material used to form the Tack component of the AbsorbaTack™ and Applicator (K071061). This absorbable polymer material is a PGLA copolymer like that used in the E-Z Tac™ (K961585). All other aspects (intended use, applicator materials, dimensions, etc) of the new Syneture™ Absorbable Tack and Applicator are identical to the predicate device AbsorbaTack™ and Applicator (K071061). The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed)" decision tree (ODE Guidance Memo # K86-3) was used to demonstrate the substantial equivalence of Syneture™ Absorbable Tack and Applicator the to the predicate device.

Administrative Information:

a.	Company Name:	United States Surgical a division of Tyco Healthcare Group LP
b.	Company Address:	150 Glover Ave. Norwalk, CT 06856
c.	Establishment Registration No:	1219161
d.	Contact Person:	Daniel Campion Associate II, Regulatory Affairs United States Surgical 150 Glover Avenue Norwalk, CT 06856
e.	Trade/Proprietary Name:	Syneture™ Absorbable Tack and Applicator
f.	Common/Usual Name:	Absorbable Tack and Applicator
g.	Classification Name:	Implantable Staple
h.	Classification Panel Name:	General and Plastic Surgery
i.	FDA Panel Number:	79
j.	Product Code:	GDW
k.	Device Class:	Class II
l.	Predicate Device(s):	AbsorbaTack™ and Applicator (K071061) E-Z Tac™ (K961585)
m.	Performance Standards:	Pursuant to Section 514 of the Act and 21 CFR Part 880, no performance standards have been established for this device.

Design and Use of the Device:

The following principal factors about the design and use of the Syneture™ Absorbable Tack and Applicator is shown in the table below.

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	√	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		√
Does the device contain components derived from a tissue or other biologic source?		√
Is the device provided sterile?	√	
Is the device intended for single use?	√	
Is the device a reprocessed single use device?		√
If yes, does this device type require reprocessed validation data?	N/A	N/A
Does the device contain a drug?		√
Does the device contain a biologic?		√
Does the device use software?		√
Does the submission include clinical information?		√
Is the device implanted?	√	

Terms used in this submission, including the use of the term "substantially equivalent" are used in the particular context of requesting a determination that the product described in this submission may be marketed in accordance with section 510(k) of the Food, Drug and Cosmetic Act. The terms and descriptions set forth in this submission are not intended to and should not have any effect on the determination of any patent infringement issue or litigation. As required by 21 CFR §807.87, this Premarket Notification, to the best of our knowledge, and all information contained here within, is truthful and accurate and no material fact has been omitted.

We consider our intent to market this device as confidential commercial information and request that it be treated as such by the FDA. We have taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information in prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

United States Surgical believes that sufficient information and data are contained in this submission to enable FDA to reach a determination of substantial equivalence within a reasonable time period. In the event that additional information is required, please contact the undersigned.

Sincerely,

Daniel Campion
Associate II, Regulatory Affairs

Telephone: (203) 492-6339
Fax: (203) 492-5029
Email: daniel.campion@tycohealthcare.com

w/attachment

4. Indications for Use Statement

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__ (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)

5. 510(k) Summary

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.

6. Truthful and Accurate Statement

Premarket Notification

Truthful and Accurate Statement

Pursuant to 21 CFR 807.87(k), I, Daniel Campion, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Associate II, Regulatory Affairs of United States Surgical, a division of Tyco Healthcare Group LP, and in reliance thereupon, the data and information submitted in this Premarket Notification are truthful and accurate and that no material fact for a review of the substantial equivalence of this device has been knowingly omitted from this submission.

Daniel Campion
Associate II, Regulatory Affairs
United States Surgical
a division of Tyco Healthcare Group LP

7/10/2007
Date

7. Class III Summary and Certification

This section does not apply.

8. Financial Certification or Disclosure Statement

This section does not apply.

9. Declarations of Conformity and Summary Reports

This section does not apply

10. Executive Summary

The Syneture™ Absorbable Tack and Applicator is offered with a range of 5 to 20 absorbable PGLA copolymer tacks. The Applicator is designed for introduction and use through a 5 mm or larger trocar sleeve for minimally invasive procedures or in open procedures.

The Absorbable Tack and Applicator is considered a modification of the predicate AbsorbaTack™ and Applicator (K071061). The modification is a change to the Absorbable Tack polymer material from a poly (L-lactide-co-D, L-lactide) (PDLA) to a poly(glycolide-co-L-lactide) (PGLA) copolymer only and all other aspects of the device will remain exactly the same. The proposed Absorbable Tack material is an absorbable synthetic polyester copolymer formed from the copolymerization of Glycolide and L-lacitde intermediates derived from lactic acid and glycolic acid like that used in the E-Z Tac™ (K961585). (b)(4) Trade Secret Process The tacks will be offered either natural or colored with D&C Violet #2 at a level not to exceed 0.2% by weight of the Tack.

United States Surgical™ has manufactured absorbable devices with PGLA copolymer material ranging (b)(4) Trade Secret Process (K821251 – Autosuture™ Absorbable Hemostatic Clip) to (b)(4) (K900122 – Autosuture™ Latchless Hemostatic Clip). Optimization of the copolymer ratio for the Syneture™ Absorbable Tack at (b)(4) (b)(4) Trade Secret has been determined. The optimal range of the proposed Syneture™ Absorbable Tack and Applicator is within the glycolide and lactide ranges that are currently used in the market today and are considered non-toxic to the patient as demonstrated by the history of use and biocompatibility testing.

11. Device Description

11.1 Product Description

Note: To facilitate this product description, a photo of the proposed device is included in Appendix 2 of this submission.

The Syneture™ Absorbable Tack and Applicator is offered with a range of 5 to 20 Absorbable PGLA Tacks. The Applicator is designed for introduction and use through a 5 mm or larger trocar sleeve for minimally invasive procedures or in open procedures. The Applicator consists of a trigger, handle and a stainless steel shaft containing Absorbable Tacks. All components and dimensions of the Applicator are exactly the same as the predicate AbsorbaTack™ Applicator (K071061).

The device is operated in the following manner. With the users off hand, counter-pressure is applied to the external location outside the body adjacent to the distal end of the shaft. The trigger is fully squeezed and the Absorbable Tack is then pushed

T9

through the prosthetic material and into the tissue. When the applicator is removed from the site the Absorbable Tack will deploy securely into the tissue and against the prosthetic material. When the trigger is released the Applicator will reset making it ready for application of the next Absorbable Tack.

11.2 Materials, Manufacture, and Sterilization

The Syneture™ Absorbable Tack and Applicator is manufactured from materials that have passed tripartite biocompatibility testing (see section 15) for their intended patient contact profile and are sterilized via a validated ethylene oxide (ETO) cycle. The Syneture™ Absorbable Tack and Applicator is manufactured in its entirety by United States Surgical in compliance with FDA's Quality Systems Regulation (QSR), 21 CFR Part 820.

The following components of the Syneture™ Absorbable Tack and Applicator are considered patient contacting components. A list of these patient contacting components and their respective materials is provided below:

Component	Material
Implantable Clip	PGLA Copolymer
Shaft	304L Stainless Steel

12. Substantial Equivalence Discussion

12.1 Identification of Predicate Device

Trade/Proprietary Name:	AbsorbaTack™ and Applicator
Common/usual name:	Absorbable Tack and Applicator
Classification name:	Implantable Staple
Class/Panel:	Class II, Title 21 CFR Section 878.4750
510(k) Submitter/Holder:	Formally Gyrx, LLC Ownership transferred to United States Surgical a division of Tyco Healthcare Group LP 150 Glover Ave. Norwalk, CT 06856
510(k) no.:	K071061

12.2 Identification of Predicate Device

Trade/Proprietary Name:	E-Z Tac™ (Surgical Dynamics Pop Rivet)
Common/usual name:	Soft Tissue Reattachment System
Classification name:	Staple, Fixation, Bone
Class/Panel:	Class II, Title 21 CFR Section 888.3030
510(k) Submitter/Holder:	United States Surgical a division of Tyco Healthcare Group LP 150 Glover Ave. Norwalk, CT 06856
510(k) no.:	K961585

12.2 Substantial Equivalence Decision Making Process

The "510(k) 'Substantial Equivalence' Decision-Making Process (Detailed)" decision tree (ODE Guidance Memo # K86-3) was used to demonstrate the substantial equivalence of the Syneture™ Absorbable Tack and Applicator to the predicate devices.

1. **Does the new device have the same indication statements?**
   Yes, the indication statement of the Absorbable Tack and Applicator is the same as the predicate device, AbsorbaTack™ and Applicator (K071061)

2. **Does the new device have the same technological characteristics, e.g., design, materials, etc.?**
   No, the Absorbable Tack in the new device is molded from PGLA copolymer which is a different polymer than the AbsorbaTack™ and Applicator (K071061) which used a PLDLA copolymer.
   The Absorbable Tack in the new device has a PGLA polymer like that used in the predicate E-Z Tac™ device (K961585).

3. **Could the new material affect safety or effectiveness?**
   No, the new Tack polymer is absorbed and excreted from the patient in the same manner as the predicate Tack polymer. Also the Absorbable Tack polymer is currently used to manufacture absorbable components of cleared devices (K821251, K900122, and K961585).

4. **Are the descriptive characteristics precise enough to ensure equivalence?**
   Yes, the results of the in vivo performance testing and biocompatibility results are precise enough to ensure equivalence.

12.3 Substantially Equivalence Comparison Matrix

Substantial Equivalence Chart

		Syneture™ Absorbable Tack and Applicator (Subject)	AbsorbaTack™ and Applicator (Predicate)	E-Z Tac™ (Predicate)
Indications for Use and Intended Use	**Indications**	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.	Identical	Not applicable
	Warnings	Identical		Not applicable
	Contraindications	Identical		Not applicable
	Precautions	Identical		Not applicable
Technological Characteristics	**Design Characteristics:**	All design characteristics are identical with exception to the polymer material of the absorbable Tack. The design and dimensions of the Applicator and Tack will remain exactly the same as the predicate.		Not applicable
	Material	PLDLA	PGLA	PGLA
	Biocompatibility	The components of the devices are manufactured from materials that have passed tripartite biocompatibility testing for their intended patient contact.		
	Packaging	The packaging of the devices is identical. The devices are placed on a plastic inset and then sealed inside a foil pouch. The foil pouch is then placed into a single applier box.		Not applicable
	Stability/Shelf Life	The devices are identical. The subject device will not be labeled with a product expiration date which is the same as the predicate device.		Not applicable

13. Proposed Labeling

A draft Instruction for Use is included in Appendix 1 of this submission.

14. Sterilization and Shelf Life

14.1 Sterilization

Pursuant to the "Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA", dated August 30, 2002 the following information is provided:

Sterilization method used: The Syneture™ Absorbable Tack and Applicator is sterilized via a validated Ethylene Oxide (EO) cycle and it is a traditional method of sterilization [Ethylene Oxide (EO) with devices placed in a fixed chamber].

Description of method used to validate the sterilization cycle: The validation conforms with AAMI/ANSI/ISO 11135:1994, "*Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization.*"

Description of the packaging used to maintain product sterility: The Syneture™ Absorbable Tack and Applicator is placed on a plastic inset and is then sealed inside a foil pouch. The foil pouch is then placed into a single applier box.

Ethylene Oxide Residuals: The evaluation of EO residuals was conducted in accordance with AAMI/ANSI/ISO 10993-7:1995, "*Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals*" and the autosuture™ Absorbable Tack and Applicator complies with allowable limits on EO residual levels as stated in AAMI/ANSI/ISO 10993-7:1995.

Pyrogenicity Evaluation: Not applicable, since this device is not labeled "pyrogen free".

Sterility Assurance Level: The sterilization cycle for the autosuture™ Absorbable Tack and Applicator will result in a minimum Sterility Assurance Level (SAL) of $1x10^{-6}$.

Radiation Dose: Not applicable, since radiation sterilization is not used for this device.

14.2 Shelf Life/Stability

At this time a shelf life will not be added to the packaging of the Absorbable Tack and Applicator.

15. Biocompatibility

The autosuture™ Absorbable Tack PGLA copolymer material has been tested to Tripartite Biocompatibility Standards prior to the "Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices (G95-1)" guidance being implemented in May of 1995. In accordance with EN/ISO 10993-1:2003 section 6, an evaluation on relevant experience and actual testing was performed on the PGLA copolymer. From this evaluation it was concluded that further testing was not needed since the material has had acceptable results in tripartite testing and has demonstrated a history of use as an implanted absorbable polymer.

16. Software

This section does not apply.

17. Electromagnetic Compatibility and Electrical Safety

This section does not apply.

18. Performance Testing – Bench

This section does not apply

19. Performance Testing - Animal

Testing was performed to evaluate the performance of the Syneture™ PGLA (a) Absorbable Tack and PGLA (b) Absorbable Tack as compared to the predicate AbsorbaTack™ and Applicator (K701061), the Syneture™ ProTack (K963999) and the Med Channel Easy Tac (K060494). PGLA (a) was an (b)(4) Trade Secret PGLA (b) was (b)(4) Trade Secret

The testing consisted of evaluation for in vivo fixation strength in porcine abdominal wall with both Gore Dual Mesh and Syneture™ Surgipro™ Polypropylene Clear Mesh. Three constructs were applied at equally spaced intervals to the end of the Mesh. The end of the mesh, opposite the constructs, was secured to a force gage and pulled in shear until failure occurred. Below is a table summarizing the results of the performance testing:

	Shear Force (kgf) with Gore Dual Mesh (1mm)				
	Test		Control		
	AbsorbaTack with PGLA-B	AbsorbaTack with PGLA-A	AbsorbaTack with PLDLA (510k Approved)	Easy Tac	ProTack
Mean	2.98	2.54	2.70	2.56	4.53
StDev	1.54	1.42	1.61	1.21	1.38
Min	1.46	0.98	1.04	1.18	2.12
Max	7.48	6.00	6.54	4.62	7.22
Sample Size	12	12	12	7	12
Specification:	Fixation force must be comparable to predicate absorbable tacks				

	Shear Force (kgf) with USS SurgiPro Polypropylene Clear Mesh			
	Test		Control	
	AbsorbaTack with PGLA-B	AbsorbaTack with PGLA-A	AbsorbaTack with PLDLA (510k Approved)	ProTack
Mean	4.14	4.17	4.20	6.00
StDev	1.60	1.42	1.73	1.09
Min	2.02	2.74	2.06	4.60
Max	7.08	7.62	8.08	8.56
Sample Size	12	12	12	12
Specification:	Fixation force must be comparable to predicate absorbable tacks			

The results of the performance testing showed that both of the PGLA materials performed equivalently to the predicate AbsorbaTack (K071061) and Med Channel Easy Tac (K060494) with regards to the in vivo fixation force. The non-absorbable ProTack (K963999) device had a higher fixation forces than each of the absorbable fixation devices.

20. Performance Evaluation - Clinical

This section does not apply.

Appendix 1

Proposed Labeling

Syneture™ Absorbable Tack and Applicator

Instruction for Use (Draft)

DRAFT

Syneture™ Absorbable Tack and Applicator

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or resterilize this device.

DESCRIPTION

The Syneture™ Absorbable Tack and Applicator are sterile, single use devices for fixation of prosthetic material, such as hernia mesh, on to soft tissue. The Absorbable Tack material is an absorbable synthetic polyester copolymer derived from a lactic and glycolic acid. The Applicator is offered with a range of 5 to 20 absorbable PGLA copolymer Tacks.

INDICATIONS

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

CONTRAINDICATIONS

The Syneture™ Absorbable Tack and Applicator is not intended for use when prosthetic material fixation is contraindicated

WARNINGS AND PRECAUTIONS

1. Procedures for endoscopic and open prosthetic fixation surgery should be performed only by qualified and trained physicians familiar with these techniques.
2. When instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure and ensure that any electrical insulation or grounding is not compromised.
3. Ensure that the Absorbable Tack and Applicator is inserted into the tissue such that the head of the tack is flush with the mesh.
4. The Absorbable Tack should be placed through the mesh and into the tissue with minimal force applied to the handle. Excessive force can result in the 5 mm shaft penetrating tissue and causing damage.
5. Do not use the Absorbable Tack and Applicator in procedures where soft tissue fixation would not normally be used.

6. Inspect the fixation site to ensure proper application.
7. The Absorbable Tack and Applicator are sterilized by Ethylene Oxide. It is a sterile, single use product and cannot be resterilized. Resterilization may compromise the integrity of the product that may result in unintended injury.
8. Data indicates that the physical characteristics and quality of this device will be adversely affected and that the device will not remain safe and effective for its intended use when cleaned and resterilized.

INSTRUCTIONS FOR USE

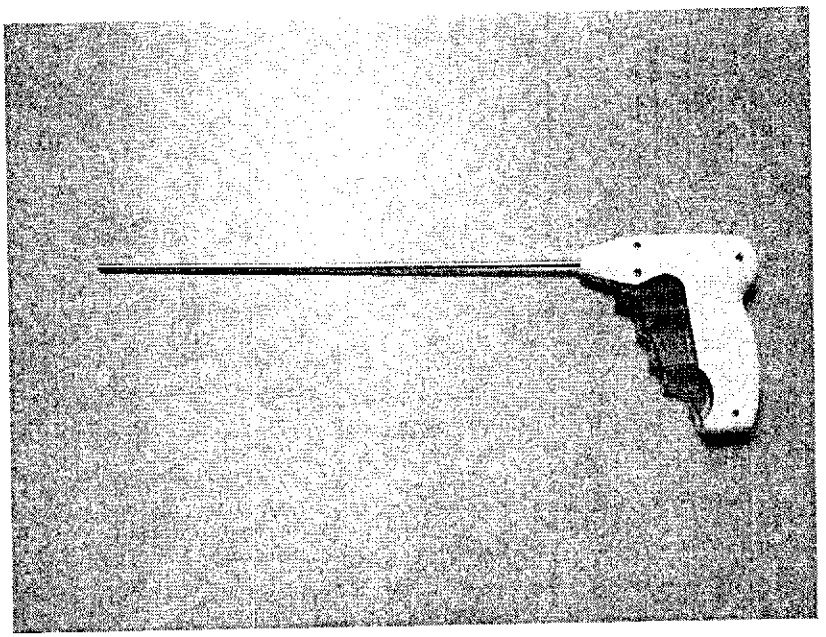
The Absorbable Tack and Applicator shaft can be inserted through a 5 mm or larger trocar cannula for use in minimally invasive procedures or the Absorbable Tack and Applicator can be used in open procedures.

Grip the handle of the Applicator and press the distal end of the shaft against the mesh at the location where fixation is desired. With the off hand (the non-applier hand) apply a counter force to the external location of outside the body immediately adjacent to the distal end of the shaft. Squeeze the trigger fully. Release the trigger and move the Applier proximal. The Absorbable Tack will be deployed securely into tissue and against the mesh. The Applicator is now ready to deploy another construct. Mesh offerings of greater thickness may require greater pressure to insure tack is inserted completely.

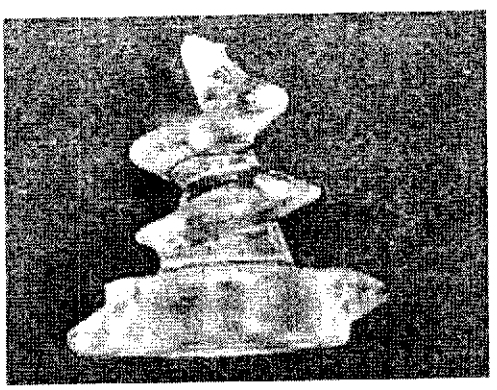
Appendix 2

Product Photo

Syneture™ Absorbable Tack and Applicator



Syneture™ Absorbable Tack Applicator



Syneture™ Absorbable Tack

™Trademark

Appendix 3

Test Report

In vivo Peak Fixation Force

(b)(4) Trade Secret

P

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Tajanay Ki

Subject: 510(k) Number K071920/S001

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

X Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			X
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)?			X
Does this device include an Animal Tissue Source?			X
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		X

Regulation Number	**Class***	**Product Code**
878.4750; Implantable Staple; Class II, GDW		

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: David Krause PRSB 9/27/07
(Branch Chief) (Branch Code) (Date)

Final Review: [signature] Neil D. R 9/27/07
(Division Director) (Date)

Rev. 7/2/07

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K071920/S001

Date: September 26, 2007
To: The Record
From: Tajanay Ki

Office: ODE
Division: DGRND

510(k) Holder: United States Surgical, a Division of Tyco Healthcare Group, LP
Device Name: Syneture™ Absorbable Tack and Applicator
Contact: Daniel Campion, Associate II, Regulatory Affairs
Phone: 203-492-6339
Fax: 203-492-5029
Email: daniel.campion@tycohealthcare.com

(b)(4) Trade Secret Process - Product Specs

Biocompatibility Data

(b)(4) Trade Secret Process - Product Specs

Device Description

(b)(4) Trade Secret Process - Product Specs

Resorption Profile

(b)(4) Trade Secret Process - Product Specs

I. Purpose

The 510(k) holder would like to introduce Syneture™ Absorbable Tack and Applicator into interstate commerce.

This device is essentially identical to the predicate K071061. The only difference is the change in the absorbable tack polymer material. The predicate is composed of poly (L-lactide-co-D, L-lactide) (PDLA), and the subject device is composed of poly(glycolide-co-L-lactide) (PGLA).

Attached to this memo please find:

- Email correspondence with the sponsor.
- Updated labeling for the device.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page: Prescription Use	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form			X

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		X	

The device is composed of absorbable tacks and an applicator. The PGLA copolymer comprising the tacks has a target (b)(4) Trade Secret Process - Product Specs [redacted] The dimensions of the tack are presented in the table below:

Characteristic	Minimum (mm)	Maximum (mm)
Total Tack Length	5.1	5.2
Tack Less Base Length	4.0	4.1
Base of Tack Length	1.0	1.1
Base Diameter	3.2	3.3

Table 1: Dimensions of Tack

The tacks will be offered either natural or colored with D&C Violet #2 at a level not to exceed 0.1% by weight of the tack. According to the 21 CFR74.1602 (Color Additive – D&C Violet No. 2), the level should not exceed 0.2% by weight. As the additive in the tack is within this level, it is not an issue. The applicator is designed for introduction and use through a 5 mm or larger trocar sleeve for minimally invasive procedures or in open procedures. The applicator consists of a trigger, handle and a stainless

steel shaft containing absorbable tacks. The system is offered in a range of 5 to 20 absorbable PGLA tacks.

III. 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 procedures, such as hernia repair.

IV. Predicate Device Comparison

- For predicate K071061, the Absorba™ Tack and Applicator is intended to are indicated for fixation of prosthetic material to soft tissue in various minimally invasive and open general surgical procedures, such as hernia repair.

  This device is identical to the subject device, except for the polymer material of the tack. It consists of an absorbable anchor and an applicator. The absorbable Anchor is formed from absorbable PLG (poly lactide and glycolide) polymers. Engineering diagram of the device is provided on page 30 (b)(4) Trade Secret Process - Product Specs [redacted]. The Applicator handle is made of plastic. The stainless steel tube contains 20 absorbable tacks.

- For predicate K961585, the E-Z Tac™ Soft Tissue Reattachment System is indicated for use in soft tissue to bone fixation for reattachment of the glenoid labrum and/or inferior glenohumeral ligament in patients with recurrent anterior dislocation of subluxation of the shoulder

(b)(4) Trade Secret Process - Product Specs [redacted]

V. Labeling

The labeling is essentially identical to the predicate K071061. (b)(4) Trade Secret Process - Product Specs [redacted].

VI. Sterilization/Shelf Life/Reuse

The sterilization procedures include:

Method: Ethylene Oxide (Traditional Method)
Validation: AAMI/ANSI/ISO 11135:1994
Packaging: The tack and applicator are placed in a plastic inset and then sealed inside a foil pouch. The foil pouch is placed inside a single applier box.
EO Residuals: complies with allowable limits on EO residual levels as stated in AAMI/ANSI/ISO 10993:7 1995
Pyrogenicity: NA
SAL: 10^{-6}

There is no shelf life indicated, as identical to the predicate.

VII. Biocompatibility

(b)(4) Trade Secret Process - Product Specs [redacted]

VIII. Software
Not Applicable

VIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety
Not Applicable

IX. Performance Testing – Bench
None

X. Performance Testing – Animal
Testing was performed to evaluate the performance of the Syneture™ PGLA Absorbable Tack as compared to the predicate AbsorbaTack™ and Applicator (K071061), the Syneture™ ProTack (963999) and the Med Channel East Tac (K060494). There were 2 formulations of the subject device used: PGLA(a) was an (b)(4) Trade Secret and PGLA(b) was an (b)(4) Trade Secret.
These two formulation are acceptable because the copolymer has a tolerance 5.0 mol % and each is within the range.

The testing consisted of evaluation for in vivo fixation strength in porcine abdominal wall with both Gore Dual Mesh and Syneture™ Surgipro™ Polypropylene Clear Mesh. (b)(4) Trade Secret Process - Product Specs The results are presented in the tables below:

Device	Mean Shear Force(kgf)	
AbsorbaTack with PGLA(a) – K071920 (subject)	2.54	(Range: 0.98-6.00)
AbsorbaTack with PGLA(b) – K071920 (subject)	2.98	(Range: 1.46-7.48)
AbsorbaTack with PLDLA – K071061 (predicate)	2.70	(Range: 1.04-6.54)
Easy Tac – K060494 (predicate)	2.56	(Range: 1.18-4.62)
ProTak – K963999 (predicate)	4.53	(Range: 2.12-7.22)

Table 1: (b)(4) Trade Secret Process -

Device	Mean Shear Force(kgf)	
AbsorbaTack with PGLA(a) – K071920 (subject)	4.17	(Range: 2.74-7.62)
AbsorbaTack with PGLA(b) – K071920 (subject)	4.14	(Range: 2.02-7.08)
AbsorbaTack with PLDLA – K071061 (subject)	4.20	(Range: 2.06-8.08)
ProTak – K963999 (subject)	6.00	(Range: 4.60-8.56)

Table 2: (b)(4) Trade Secret Process - Product Specs

The results show that the subject device was basically equivalent to AbsorbaTack with PDLA and Easy Tac in terms of shear force. The shear force for ProTak was superior to all the samples. As the subject device performed comparably to the other devices, the results are acceptable.

XI. Performance Testing – Clinical
Not Applicable

3

XII. Substantial Equivalence Discussion

	Yes	No	
1. Is Product A Device	X		If **NO** = Stop, see 510(k) staff
2. Is Device Subject To 510(k)?	X		If **NO** = Stop, see 510(k) staff
3. Same Indication Statement?	X		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
5. Same Technological Characteristics?	X		If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?		X	If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
10. Performance Data Available?	X		If **NO** = Request Data
11. Data Demonstrate Equivalence?	X		Final Decision: SE

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification 510kProgram/0_4147/FLOWCHART 510K DECISION.PDF for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. Explain how the new indication differs from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:
It was necessary to review the data.

8. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
The data demonstrate that the subject device is substantially equivalent to the predicates.

XIII. Deficiencies

Not Applicable

XIV. **Contact History**

(b)(4) Trade Secret Process - Product Specs

XV. **Recommendation**

Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW

Reviewer — Date: 9/26/07

Branch Chief — Date: 9/27/07

Ki, Tajanay R

From: Campion, Daniel [Daniel.Campion@Covidien.com]
Sent: Tuesday, September 25, 2007 3:35 PM
To: Ki, Tajanay R
Subject: RE: K071920
Attachments: Proposed Labeling Draft - 9-25-07 with FDA updates.doc

Hi Mrs Ki,

(b)(4) Trade Secret Process

[redacted]

Dan Campion

Daniel Campion
Regulatory Affairs Associate II
Covidien
60 Middletown Ave
North Haven, CT, 06473
United States

Office: (203) 492-6339
Fax: (203) 492-5029
www.covidien.com http://www.covidien.com

From: Ki, Tajanay R [mailto:tajanay.ki@fda.hhs.gov]
Sent: Tuesday, September 25, 2007 12:21 PM
To: Campion, Daniel
Subject: K071920

Hi Mr. Campion:

(b)(4) Trade Secret Process

[redacted]

(b)(4) Trade Secret Process

[redacted]

Thank you,
Tajanay

Tajanay Ki, Biomedical Engineer
Plastic and Reconstructive Surgery Devices Branch
U.S. Food and Drug Administration
9200 Corporate Blvd, HFZ-410
Rockville, MD 20850
(240) 276-3625 (voice)
(240) 276-3733 (fax)
tajanay.ki@fda.hhs.gov

SYNETURE™ ABSORBATACK™

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection. **Do not reuse, reprocess or resterilize this device.**

DESCRIPTION

The Syneture™ AbsorbaTack™ device is a sterile, single use device for fixation of prosthetic material, such as hernia mesh, on to soft tissue. The Absorbable Tack material is an absorbable synthetic polyester copolymer derived from a lactic and glycolic acid. The Applicator is offered with a range of 5, 10 or 20 absorbable PGLA copolymer Tacks either natural or colored with D&C Violet #2 at a concentration not to exceed 0.1% by weight of the tack.

INDICATIONS

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

CONTRAINDICATIONS

The Syneture™ AbsorbaTack™ Absorbable Tack and Applicator is not intended for use when prosthetic material fixation is contraindicated

WARNINGS AND PRECAUTIONS

1. Procedures for endoscopic and open prosthetic fixation surgery should be performed only by qualified and trained physicians familiar with these techniques.
2. When instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure and ensure that any electrical insulation or grounding is not compromised.
3. Ensure that the Syneture™ AbsorbaTack™ is inserted into the tissue such that the head of the tack is flush with the mesh.
4. The Syneture™ AbsorbaTack™ tack should be placed through the mesh and into the tissue with minimal force applied to the handle. Excessive force can result in the 5 mm shaft penetrating tissue and causing damage.
5. Do not use The Syneture™ AbsorbaTack™ device in procedures where soft tissue fixation would not normally be used.
6. Inspect the fixation site to ensure proper application.
7. The Syneture™ AbsorbaTack™ device is sterilized by Ethylene Oxide. It is a sterile, single use product and cannot be resterilized. Resterilization may compromise the integrity of the product that may result in unintended injury.
8. Data indicates that the physical characteristics and quality of this device will be adversely affected and that the device will not remain safe and effective for its intended use when cleaned and resterilized.

INSTRUCTIONS FOR USE

The Syneture™ AbsorbaTack™ device shaft can be inserted through a 5 mm or larger trocar cannula

for use in minimally invasive procedures or the AbsorbaTack™ tack can used in open procedures.

Grip the handle of the AbsorbaTack™ device and press the distal end of the shaft against the mesh at the location where fixation is desired. With the off hand (the non-applier hand) apply a counter force to the external location outside the body immediately adjacent to the distal end of the shaft. Squeeze the trigger fully. Release the trigger and move the AbsorbaTack™ device proximal. The AbsorbaTack™ tack will be deployed securely into tissue and against the mesh. The AbsorbaTack™ device is now ready to deploy another Tack. Mesh offerings of greater thickness may require greater pressure to insure tack is inserted completely.

EFFECTS

The tack is made of the common copolymer poly(glycolide-co-L-lactide) (PGLA). This copolymer degrades and is absorbed by hydrolysis to glycolic acid and lactic acid which are then metabolized by the body.

The absorption profile of Poly(glycolide-co-L-lactide) (PGLA) in the first two weeks after initial implantation is minimal with a significant absorption rate seen in the period from 3 months to 5 months. Following this significant breakdown the polymer absorption is essentially completed prior to one year

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

MOA for DXK
9/11/07

From: Reviewer Name Tajanay Ki

Subject: 510(k) Number K071920

To: The Record

Please list CTS decision code AI

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- X Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)?			
Does this device include an Animal Tissue Source?			
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number	**Class***	**Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: _____ _____ _____
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

Rev. 7/2/07

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K071920

Date: September 10, 2007
To: The Record
From: Tajanay Ki

Office: ODE
Division: DGRND

510(k) Holder: United States Surgical, a Division of Tyco Healthcare Group, LP
Device Name: Syneture™ Absorbable Tack and Applicator
Contact: Daniel Campion, Associate II, Regulatory Affairs
Phone: 203-492-6339
Fax: 203-492-5029
Email: daniel.campion@tycohealthcare.com

I. Purpose

The 510(k) holder would like to introduce Autosuture™ Absorbable Tack and Applicator into interstate commerce.

This device is essentially identical to the predicate K071061. The only difference is the change in the absorbable tack polymer material. The predicate is composed of poly (L-lactide-co-D, L-lactide) (PDLA), and the subject device is composed of poly(glycolide-co-L-lactide) (PGLA).

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page: Prescription Use	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form			X

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?	X		

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	Yes	No	N/A
Is the device reusable (not reprocessed single use)?			
Are "cleaning" instructions included for the end user?		X	

The device is composed of absorbable tacks and an applicator. The PGLA copolymer comprising the tacks has (b)(4) Trade Secret Process respectively, with a (b)(4) Trade Secret Process. The dimensions of the tack are not clear. The tacks will be offered either natural or colored with D&C Violet #2 at a level not to exceed 0.2% by weight of the tack. The applicator is designed for introduction and use through a 5 mm or larger trocar sleeve for minimally invasive procedures or in open procedures. The applicator consists of a trigger, handle and a stainless steel shaft containing absorbable tacks. The system is offered in a range of 5 to 20 absorbable PGLA tacks.

(b)(4) Trade Secret Process

III. 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 procedures, such as hernia repair.

IV. Predicate Device Comparison

- For predicate K071061, the Absorba™ Tack and Applicator is intended to are indicated for fixation of prosthetic material to soft tissue in various minimally invasive and open general surgical procedures, such as hernia repair.

  This device is identical to the subject device, except for the polymer material of the tack. It consists of an absorbable anchor and an applicator. The absorbable Anchor is formed from absorbable PLG (poly lactide and glycolide) polymers. Engineering diagram of the device is provided on page 30. (b)(4) Trade Secret Process. The Applicator handle is made of plastic. The stainless steel tube contains 20 absorbable tacks.

- For predicate K961585, the E-Z Tac™ Soft Tissue Reattachment System is indicated for use in soft tissue to bone fixation for reattachment of the glenoid labrum and/or inferior glenohumeral ligament in patients with recurrent anterior dislocation of subluxation of the shoulder

  (b)(4) Trade Secret Process

V. Labeling

The labeling is identical to the predicate K071061. The labeling does not contain the absorption information for the absorbable tack. (b)(4) Trade Secret Process.

VI. Sterilization/Shelf Life/Reuse

The sterilization procedures include:

Method: Ethylene Oxide (Traditional Method)
Validation: AAMI/ANSI/ISO 11135:1994
Packaging: The tack and applicator are placed in a plastic inset and then sealed inside a foil pouch. The foil pouch is placed inside a single applier box.
EO Residuals: complies with allowable limits on EO residual levels as stated in AAMI/ANSI/ISO 10993:7 1995
Pyrogenicity: NA

SAL: 10^{-6}
There is no shelf life indicated, as identical to the predicate.

VII. Biocompatibility
The sponsor states that the autosuture™ Absorbable Tack PGLA copolymer material has been tested to Tripartite Biocompatibility Standards. They also state that an evaluation on relevant experience and actual testing was performed on the PGLA copolymer. They conclude that due to the acceptable results in tripartite testing and a history of use as an implantable polymer, no biocompatibility testing was completed.

(b)(4) Trade Secret Process

[redacted]

VIII. Software
Not Applicable

VIII. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety
Not Applicable

IX. Performance Testing – Bench
None

X. Performance Testing – Animal
Testing was performed to evaluate the performance of the Syneture™ PGLA Absorbable Tack as compared to the predicate AbsorbaTack™ and Applicator (K071061), the Syneture™ ProTack (963999) and the Med Channel East Tac (K060494). There were 2 formulations of the subject device used: PGLA(a) was an (b)(4) Trade Secret and PGLA(b) was an (b)(4) Trade Secret.
These two formulation are acceptable because the copolymer has a tolerance 5.0 mol % and each is within the range.

The testing consisted of evaluation for in vivo fixation strength in porcine abdominal wall with both Gore Dual Mesh and Syneture™ Surgipro™ Polypropylene Clear Mesh. Three constructs were applied at equally spaced intervals to the end of the mesh. The end of the mesh, opposite the constructs was secured to a force gage and pulled in shear until failure occurred. The results are presented in the tables below:

Device	Mean Shear Force(kgf)	
AbsorbaTack with PGLA(a) – K071920 (subject)	2.54	(Range: 0.98-6.00)
AbsorbaTack with PGLA(b) – K071920 (subject)	2.98	(Range: 1.46-7.48)
AbsorbaTack with PLDLA – K071061 (predicate)	2.70	(Range: 1.04-6.54)
Easy Tac – K060494 (predicate)	2.56	(Range: 1.18-4.62)
ProTak – K963999 (predicate)	4.53	(Range: 2.12-7.22)

Table 1: Testing results using Gore Dual Mesh

Device	Mean Shear Force(kgf)	
AbsorbaTack with PGLA(a) – K071920 (subject)	4.17	(Range: 2.74-7.62)
AbsorbaTack with PGLA(b) – K071920 (subject)	4.14	(Range: 2.02-7.08)
AbsorbaTack with PLDLA – K071061 (subject)	4.20	(Range: 2.06-8.08)
ProTak – K963999 (subject)	6.00	(Range: 4.60-8.56)

Table 2: Testing results using USS SurgiPro Polypropylene Clear Mesh

The results show that the subject device was basically equivalent to AbsorbaTack with PDLA and Easy Tac in terms of shear force. The shear force for ProTak was superior to all the samples. As the subject

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device performed comparably to the other devices, the results are acceptable.

XI. Performance Testing – Clinical

Not Applicable

XII. Substantial Equivalence Discussion

	Yes	No	
1. Is Product A Device	X		If **NO** = Stop, see 510(k) staff
2. Is Device Subject To 510(k)?	X		If **NO** = Stop, see 510(k) staff
3. Same Indication Statement?	X		If **YES** = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
5. Same Technological Characteristics?	X		If **YES** = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 8
7. Descriptive Characteristics Precise Enough?		X	If **NO** = Go To 10 If **YES** = Stop **SE**
8. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
9. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
10. Performance Data Available?		X	If **NO** = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification 510kProgram/0_4147/FLOWCHART 510K DECISION.PDF for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. Explain how the new indication differs from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:
It was necessary to review the data.

8. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:
Biocompatibility data, updated labeling and the resorption profile.

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

(b)(4) Trade Secret Process

[redacted]

XIV. Contact History

XV. Recommendation

Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW

Reviewer — Date: 9/10/07

Branch Chief — Date: 9/11/07

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

September 19, 2007

UNITED STATES SURGICAL, A DIVISION
150 GLOVER AVE.
NORWALK, CT 06856
ATTN: DANIEL CAMPION

510(k) Number: K071920
Product: AUTOSUTURE ABSORBABLE TACK AND APPLICATOR

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K071920/S1

COVIDIEN

September 18, 2007

Food and Drug Administration
Centers for Device and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville Maryland 20850

Subject: K071920
Additional Information for:
Traditional 510(k): Device Modification (21 CFR 807.90(e))
Syneture™ Absorbable Tack and Applicator

Dear Madam or Sir:

(b)(4) Trade Secret Process

[redacted]

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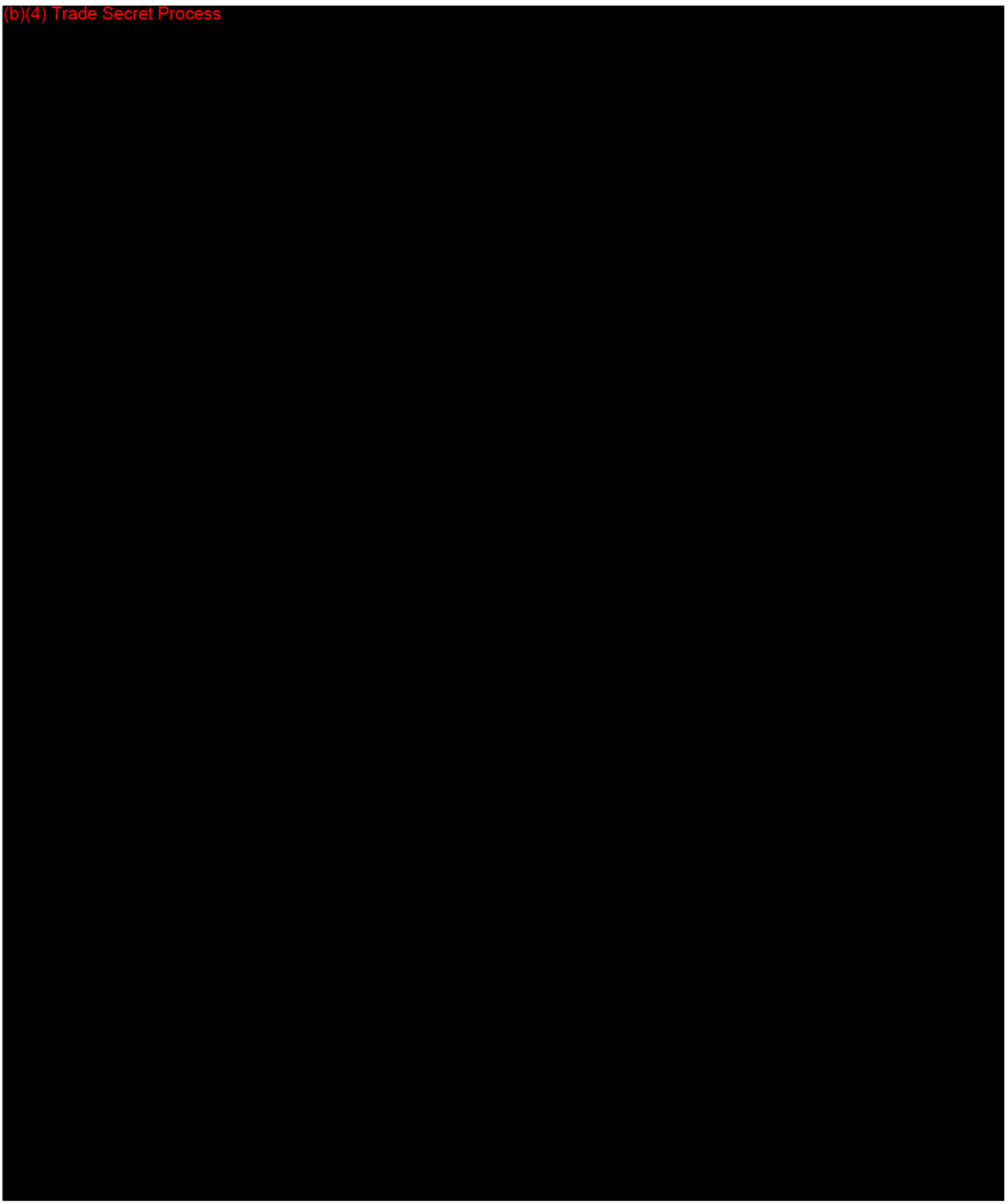
(b)(4) Trade Secret Process



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(b)(4) Trade Secret Process

[redacted]

Please feel free to contact me at if there are any questions or concerns with the responses above. Thank you and best regards,

Daniel Campion
Regulatory Affairs Associate II
Covidien
60 Middletown Ave
North Haven, CT, 06473
United States

Office: (203) 492-6339
Fax: (203) 492-5029