



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (Idt)

FOLDER: K900129 - 48 pages

COMPANY: UNITED STATES SURGICAL (UNITSTATSURG)

PRODUCT: STAPLE, IMPLANTABLE (GDW)

SUMMARY: Product: MODIFIED AUTO SUTURE ENDOSCOPIC GIA SURG.
STAPLER*

DATE REQUESTED: Oct 9, 2014

DATE PRINTED: Oct 9, 2014

Note: Printed





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 27 1990

 Food and Drug Administration
 1390 Piccard Drive
 Rockville, MD 20850

Mr. Steve Reitzler
 Director, Regulatory Affairs
 United States Surgical Corporation
 150 Glover Avenue
 Norwalk, Connecticut 06856

Re: K900129
 Modified Auto Suture^R
 Endoscopic GIATM Surgical
 Stapler
 Regulatory Class: II
 Dated: February 12, 1990
 Received: February 16, 1990

Dear Mr. Reitzler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) 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 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Carl A. Larson

Carl A. Larson, Ph.D.
 Director,
 Division of Surgical
 and Rehabilitation Devices
 Office of Device Evaluation
 Center for Devices and
 Radiological Health

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date: 2/21/90

From: REVIEWER(S) - NAME(S) Bruno M. Mueland

Subject: 510(k) NOTIFICATION K900129 / A

To: THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

see attached memo
2/21/90

The submitter requests under 21 CFR §807.95:

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code w/Panel and class:

79 MDW, Class II

Additional Product Code(s) w/Panel (optional):

REVIEW:

Bruno Mueland
for (BRANCH CHIEF)

2/23/90
(DATE)

FINAL REVIEW:

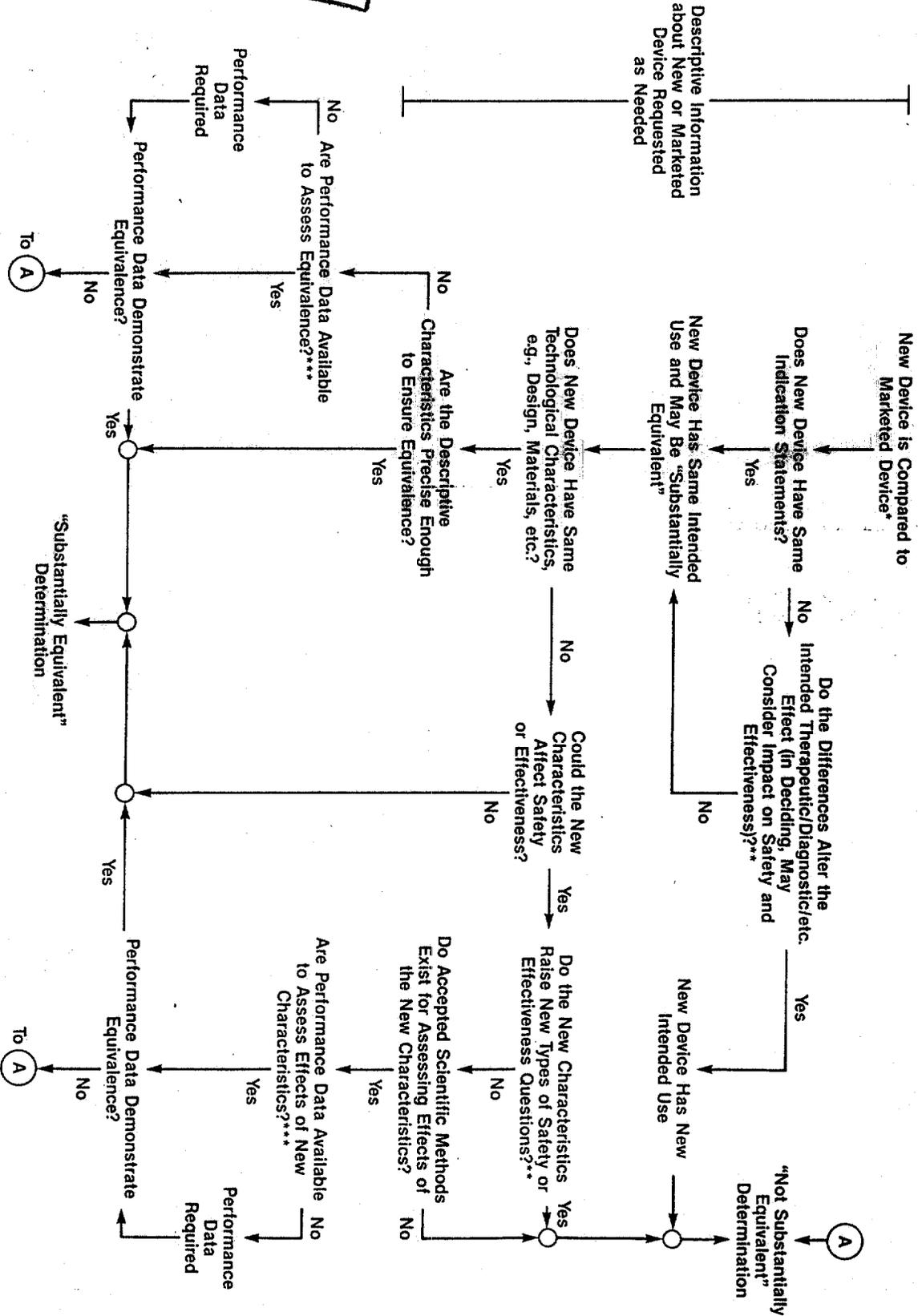
Kenneth Palmer
for (DIVISION DIRECTOR)

2/27/90
(DATE)

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510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



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* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.
 *** Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

MEMO TO THE RECORD
510(k) REVIEW
K900129

DATE: 2/21/90
FROM: BIOLOGIST

OFFICE: HFZ-410
DIVISION: DSRD/SDB

COMPANY NAME: United States Surgical Corporation
DEVICE NAME: Modified Auto Suture Endoscopic GIA Surgical Stapler

1. Life-supporting or life-sustaining? yes
2. Implant (short-term or long-term)? yes, permanent
3. Software-driven? N/A
4. Device(s) to which equivalence is claimed and manufacturer:
K892233, same as above, only not modified.
5. Submission provides comparative specifications: yes
comparative in vitro data: N/A
summary of animal testing: N/A
summary of clinical testing: N/A
6. Description of device and its differences from pre-enactment/predicate device(s), including indications for use, new technology and potential safety issues: The device is a surgical stapler that is indicated for use in endoscopic, gynecological, and general abdominal procedures for the transection and resection of tissues. The device is composed of a disposable stapler and loading unit. Previously, the predicate device was composed of a re-useable stainless steel sterile stapler with a disposable single-use stapling unit. This submission is requesting amendment of this original submission to permit modification of the device so that it becomes a totally disposable device. In addition, the sponsor has also requested that he be allowed to add an additional staple size (a larger staple that will accomodate thicker tissues). This size addition is not a problem since this staple size (3.5mm staple leg prior to closure) is already on the market with another type of staple device (TA*30 PREMIUM 3.5 surgical stapler) that is also manufactured by USSC. The device sterilization, indications for use, method of packaging and labeling (with the exception of the "disposable" issues) etc., all remain the same as that of the predicate device.
7. Recommendation: Based on the information contained in this submission, I recommend a finding of substantial equivalence for this device.
8. Classification: Class II
Product Code GDW

21 CFR 878.4750, Implantable Staple

Frances M. Moreland

Frances M. Moreland
Plastic and Reconstructive Surgery Devices Section
Division of Surgical and Rehabilitative Devices

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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)
1390 Piccard Drive
Rockville, Maryland 20850

FEBRUARY 16, 1990

UNITED STATES SURGICAL CORP.
ATTN: CURTIS RAYMOND
150 GLOVER AVENUE
NORWALK, CT 06856

D.C. Number : K900129
Received : 02-16-90
90th Day : 05-17-90
Product : MODIFIED AUTO
SUTURE ENDOSCOPIC
GIA SURG. STAPLER*

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. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

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United States Surgical Corporation

150 Glover Avenue, Norwalk, Connecticut 06856 (203) 866-5050

K900129/A

FDA-CR-89-057

FEB 16 1990

DOCUMENT MAIL CENTER

February 12, 1990

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Attn: Fran Moreland
Division of Surgical and Rehabilitation Devices (HFZ-410)

Reference: 510(k) No. K900129, DISPOSABLE ENDOSCOPIC GIA™ Stapler*

Dear Ms. Moreland:

This submission is in response to your telephone call of February 6, 1990, wherein you requested additional information to aid in your review of the above referenced 510(k) notification. In accordance with your request, we attach herewith the following additional information:

A description of the packaging for the subject device. Said packaging is identical in design and materials to that used to package other currently marketed Auto Suture® disposable surgical staplers and disposable loading units, including the disposable loading unit designed for use with the stainless steel version of the subject device described in 510(k) notification no. K892233.

A description of the method of sterilization of the subject device. Said method is identical to that employed to sterilize other currently marketed Auto Suture® disposable surgical staplers and disposable loading units, including the disposable loading unit designed for use with the stainless steel version of the subject device described in 510(k) notification no. K892233.

*Trademark name not yet determined.

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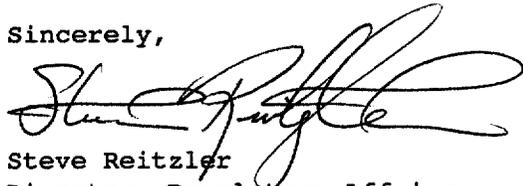
6

-2-

Complete draft labeling for the subject device, consisting of an information booklet, the unit package label, and the display box (multi pack) labeling. For purposes of comparison, we have also attached the draft labeling for the stainless steel form of the device, as was originally contained in 510(k) notification K892233. As can be seen, the only labeling changes consist of those describing the new 3.5 size staple, and those associated with use of the wholly disposable instrument as opposed to the permanent instrument and loading unit system described in 510(k) no. K892233.

Ms. Moreland, we trust that the information attached herewith proves sufficient to assist in completion of the Agency's review of the subject premarket notification for the DISPOSABLE ENDOSCOPIC GIA™ Surgical Stapler*.

Sincerely,



Steve Reitzler
Director, Regulatory Affairs
SR:rr

Enclosure

*Trademark name not yet determined.

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PACKAGING

The unit package for the DISPOSABLE ENDOSCOPIC GIA™ Surgical Stapler* consists of a (b) (4) blister to which is sealed a (b) (4) TYVEK® blister lid. One dozen such units packages will be contained within a display box (multi pack), and an information booklet will be provided with each display box. This package configuration is identical in materials and design to that used to package many other currently marketed Auto Suture® disposable stapling instruments and loading units, including the disposable loading unit used with the stainless steel version of the subject device described in 510(k) notification number K892233.

*Trademark name not yet determined.

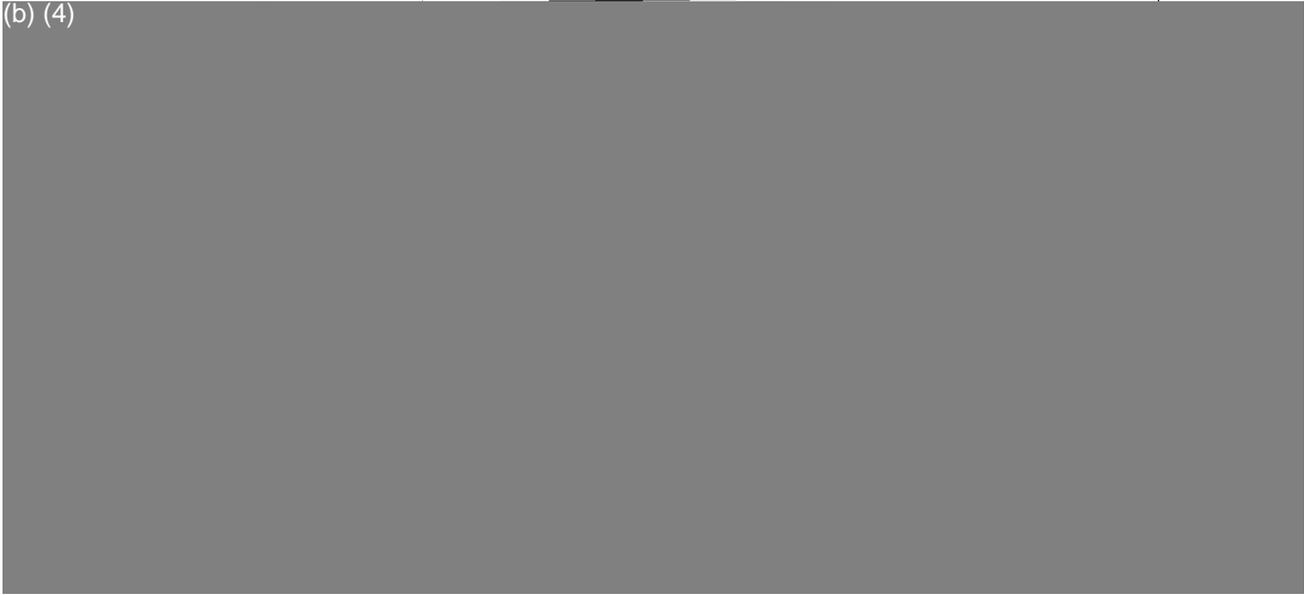
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STERILIZATION

The subject DISPOSABLE ENDOSCOPIC GIA™ Surgical Stapler* is

(b) (4)



The sterilization and release of the DISPOSABLE ENDOSCOPIC GIA™ Surgical Stapler* will be performed in the same manner as other currently marketed Auto Suture® disposable surgical staplers and loading units, including the disposable loading unit used with the stainless steel version of the subject device described in 510(k) notification number K892233.

*Trademark name not yet determined.

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DRAFT LABELING

Provided on the following pages is draft labeling for the subject DISPOSABLE ENDOSCOPIC GIA™ Surgical Stapling Instrument*, including an information booklet for the subject device, and both unit package and display box (multi-pack) labeling, the latter represented by the instrument containing the "V" size staple. To assist in review of this labeling, we also include draft labeling for the stainless steel version of the device as was originally described in 510(k) notification number K892233.

It may be seen from this comparison that the only changes in the proposed labeling for the disposable form of the subject device consist of the addition of information describing the new "3.5" size staple, and changes related to use of the wholly disposable instrument as opposed to the stainless steel instrument/loading unit system described in 510(k) notification number K892233.

*Trademark name not yet determined.

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DISPOSABLE INSTRUMENT UNIT PACKAGE

PEEL DOWN

Auto Suture®
DISPOSABLE ENDOSCOPIC GIA™-V
Surgical Stapling Instrument*

Reorder Number

(Artwork)

Contains one disposable surgical stapling instrument with integral cartridge. The stapling instrument contains 46 staples of 0.21mm diameter stainless steel wire arranged in two triple staggered rows 31.0mm long, and has an integral knife blade which cuts between the triple rows. The staple leg length is 2.5mm before closure, and the staple height is approximately 1.0mm when closed.

**STERILE/SINGLE USE ONLY
DO NOT RESTERILIZE/DISCARD AFTER USE.**

Unless opened or damaged, contents of each package sterile.

READ INFORMATION BOOKLET BEFORE USE.

CAUTION: Federal (U.S.A.) law restricts this device to sale, distribution, and use by, or on, the order of a physician.

LOT NUMBER:

EXP.:

Manufactured by United States Surgical Corporation
Norwalk, Connecticut, 06856

*Trademark name not yet determined.

BEST AVAILABLE COPY

DISPLAY BOX - FRONT PANEL

Auto Suture®
DISPOSABLE ENDOSCOPIC GIA™-V
Surgical Stapling Instrument*

Reorder Number

(Artwork)

Contains twelve disposable surgical stapling instruments with integral cartridge. Each surgical stapler contains 46 staples of 0.21mm diameter stainless steel wire arranged in two triple staggered rows 31.0mm long, and has an integral knife blade which cuts between the triple rows. The staple leg length is 2.5mm before closure, and the the staple height is approximately 1.0mm when closed.

STERILE/SINGLE USE

Unless opened or damaged, contents of each package sterile,

DO NOT RESTERILIZE

CAUTION: Federal (U.S.A.) law restricts this device to sale, distribution, and use by, or on, the order of a physician.

Manufactured by United States Surgical Corporation
Norwalk, Connecticut 06856

*Trademark name not yet determined.

BEST AVAILABLE COPY

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DISPLAY BOX - SIDE PANELS

Auto Suture®
DISPOSABLE ENDOSCOPIC GIA™-V
Surgical Stapling Instrument*

Reorder Number

(Artwork)

Contains twelve disposable surgical stapling instruments.

**STERILE/SINGLE USE
DO NOT RESTERILIZE**

Unless opened or damaged, contents of each package sterile.

READ INFORMATION BOOKLET BEFORE USE

*Trademark name not yet determined.

BEST AVAILABLE COPY

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DISPLAY BOX - REAR PANEL

Auto Suture®
DISPOSABLE ENDOSCOPIC GIA™-V
Surgical Stapling Instrument*

Reorder Number

(Artwork)

(BAR CODE)

LOT NUMBER:

EXP.:

*Trademark name not yet determined.

BEST AVAILABLE COPY

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INFORMATION BOOKLET FOR

**Auto Suture®
DISPOSABLE ENDOSCOPIC GIA™
Surgical Stapling Instruments***

(Artwork)

Important

This booklet is designed to assist in using the Auto Suture® DISPOSABLE ENDOSCOPIC GIA™ Surgical Stapling Instruments*. It is not a reference to endoscopic surgical stapling techniques. For information on surgical stapling techniques please see Endoscopy in Gynecology, J. M. Phillips, MD (Editor-in-Chief), Department of Publications, American Association of Gynecological Laparoscopists, Copyright 1978.

READ ALL INFORMATION CAREFULLY

CAUTION: Federal (U.S.A.) law restricts this device to sale, distribution, and use by, or on, the order of a physician.

*Trademark name not yet determined.

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Auto Suture®
DISPOSABLE ENDOSCOPIC GIA™
Surgical Stapling Instrument*

Indications:

The Auto Suture® DISPOSABLE ENDOSCOPIC GIA™ Surgical Stapler* has application in endoscopic, gynecologic, and general abdominal procedures for the transection and resection of tissues.

Effects:

The DISPOSABLE ENDOSCOPIC GIA™ Surgical Stapler* places two triple staggered rows of stainless steel staples, and simultaneously divides the tissue between the two triple rows. The size of the staple is determined by the selection of the V or 3.5 stapler.

Schematic View and Nomenclature

Auto Suture® DISPOSABLE ENDOSCOPIC GIA™ Surgical Stapler*

(Artwork)

*Trademark name not yet determined.

BEST AVAILABLE COPY

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Instructions for Use

Auto Suture®

DISPOSABLE ENDOSCOPIC GIA™ Surgical Stapling Instrument*

1. With the disposable surgical stapler cartridge forks closed (the instrument clamping lever is flush against the body of the stapler), gently introduce the stapler through the trocar sleeve.

(Artwork)

2. Open the cartridge forks by opening the clamping lever of the surgical stapler. Place the cartridge forks across the tissue to be transected, or insert the fork into the lumen of the structure to be anastomosed.

(Artwork)

3. Close the clamping lever completely. An audible click will signify that the stapler is properly closed. Inspect the tissue for desired position within the cartridge forks. If necessary, open the clamping lever, reposition the tissue, and close the clamping lever again before firing the surgical stapler.

(Artwork)

*Trademark name not yet determined.

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4. To fire the surgical stapler, place thumb on the plunger located at the proximal end of the instrument. Compress the plunger as far as it will go (until flush with the instrument body), and then release.

Note: Do not use the DISPOSABLE ENDOSCOPIC GIA™ Surgical Stapler* on structures which cannot be visually inspected for hemostasis after application.

(Artwork)

5. Open the instrument clamping lever to release the tissue from the cartridge forks. Gently remove the instrument from the trocar sleeve. Always inspect the staple lines for hemostasis.

(Artwork)

6. Discard the surgical stapler after use. Never reuse the disposable surgical stapler.

*Trademark name not yet determined.

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DISPOSABLE ENDOSCOPIC GIA™ Surgical Stapler* Information

DISPOSABLE ENDOSCOPIC GIA™-V Surgical Stapler*

The integral cartridge contains 46 staples of 0.21mm diameter stainless steel wire arranged in two triple staggered rows 31.0mm long. The two sets of staple lines are approximately 3.0mm apart. An integral knife blade divides the tissue between the two triple rows of staples. The knife cut will end approximately 5mm short of the distal end of the staple rows. The staple leg length is 2.5mm before closure, and the staple height is approximately 1.0mm when closed. The preformed staple leg is a specific length; however, the height and shape of the closed staple may vary according to tissue thickness.

(Artwork)

DISPOSABLE ENDOSCOPIC GIA™-3.5 Surgical Stapler*

The integral cartridge contains 34 staples of 0.23mm diameter stainless steel wire arranged in two triple staggered rows 31.0mm long. The two sets of staple lines are approximately 3.5mm apart. An integral knife blade divides the tissue between the two triple rows of staples. The knife cut will end approximately 5mm short of the distal end of the staple rows. The staple leg length is 3.5mm before closure, and the staple height is approximately 1.5mm when closed. The preformed staple leg is a specific length; however, the height and shape of the closed staple may vary according to tissue thickness.

(Artwork)

*Trademark name not yet determined.

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CAUTIONS AND CONTRAINDICATIONS

Cautions:

1. Make sure the cartridge forks of the disposable surgical stapler are closed before introducing the instrument through a trocar sleeve.
2. Prior to firing, the instrument clamping lever must be completely closed against the instrument body (listen for audible click).
3. When applying the ENDOSCOPIC GIA™ Surgical Stapler* across tissue or into the lumen of organs to be anastomosed, make certain that the tissue is properly positioned and aligned in the forks, and that no extraneous tissue has been incorporated. Tissue should not extend below the "3cm" mark at the proximal end of the cartridge forks.
4. After firing, always inspect the staple lines for hemostasis. Minor bleeding may be controlled by means of electrocautery or by manual suture.
5. Discard the DISPOSABLE ENDOSCOPIC GIA surgical stapler* immediately after use. Never reuse the disposable surgical stapling instrument.
6. Endoscopic procedures should be performed only by persons having adequate training and familiarity with endoscopic techniques. Consult the medical literature relative to techniques, complications and hazards, prior to performance of any endoscopic procedure.
7. When endoscopic instruments and accessories from different manufacturers are employed together in a procedure, verify their compatibility, and ensure that electrical isolation or grounding is not compromised.
8. A thorough understanding of the principles and techniques involved in laser laparoscopy and electrosurgical procedures is essential to avoid shock and burn hazards to both the patient and operator(s), and damage to the instruments.

READ ALL INSTRUCTIONS CAREFULLY.

Contraindications:

1. Do not use the DISPOSABLE ENDOSCOPIC GIA™-V Surgical Stapler* on any tissue that compresses to less than 1.0mm in thickness. In such cases, the staple may not be tight enough to ensure hemostasis.

*Trademark name not yet determined.

BEST AVAILABLE COPY

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2. Do not use the DISPOSABLE ENDOSCOPIC GIA™-V Surgical Stapler* on tissue which cannot compress comfortably to 1.0mm in thickness. In such cases the tissue is too thick for the staple size. However, the 3.5 staple size may be used.
3. Do not use the DISPOSABLE ENDOSCOPIC GIA™-3.5 Surgical Stapler* on tissue that compresses to less than 1.5mm in thickness. In such cases, the staple may not be tight enough to ensure hemostasis. However, the V staple size may be used.
4. Do not use the DISPOSABLE ENDOSCOPIC GIA™-3.5 Surgical Stapler* on tissue which cannot compress comfortably to 1.5mm in thickness. In such cases the tissue is too thick for the staple size.
5. The stapler should not be used on tissue such as liver or spleen, where compressibility is such that closure of the instrument forks would be destructive.
6. Do not use the stapler where adequacy of hemostasis cannot be verified visually after application.

Sterilization:

Auto Suture® DISPOSABLE ENDOSCOPIC GIA™ Surgical Staplers* are supplied sterile, and intended for single use only. Discard after use. DO NOT RESTERILIZE.

Manufactured by:
UNITED STATES SURGICAL CORPORATION
Norwalk, Connecticut 06856 Made in USA

*Trademark name not yet determined.

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JH

INSTRUMENT UNIT PACKAGE

Contains One

Auto Suture®
ENDOSCOPIC GIA™ Surgical Stapler*

Reorder Number

(Artwork)

(Bar Code)

SERIAL NUMBER

CAUTION: Federal (U.S.A.) law restricts this device to sale,
distribution, and use by, or on, the order of a physician.

Manufactured by United States Surgical Corporation
Norwalk, Connecticut 06856 Made in USA

*Trademark name not yet determined.

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D.L.U. UNIT PACKAGE

PEEL DOWN

Auto Suture®
ENDOSCOPIC GIA™-V Disposable Loading Unit*

Reorder Number

(Artwork)

For use with Auto Suture® ENDOSCOPIC GIA™ Surgical Stapler*

Contains one disposable loading unit with integral knife blade. The loading unit contains 46 staples of 0.21mm diameter stainless steel wire arranged in two triple staggered rows 31.0mm long, and has an integral knife blade which cuts between the triple rows. The staple leg length is 2.5mm before closure, and the staple height is approximately 1.0mm when closed.

STERILE/SINGLE USE ONLY
DO NOT RESTERILIZE/DISCARD AFTER USE.

Unless opened or damaged, contents of each package sterile.

READ INFORMATION BOOKLET BEFORE USE.

CAUTION: Federal (U.S.A.) law restricts this device to sale, distribution, and use by, or on, the order of a physician.

LOT NUMBER:

EXP.:

Manufactured by United States Surgical Corporation
Norwalk, Connecticut, 06856

*Trademark name not yet determined.

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DISPLAY BOX - FRONT PANEL

**Auto Suture®
ENDOSCOPIC GIA™-V Disposable Loading Unit***

Reorder Number

(Artwork)

For use with Auto Suture® ENDOSCOPIC GIA™ Surgical Stapler*.

Contains twelve disposable loading units with integral knife blade. Each disposable loading unit contains 46 staples of 0.21mm diameter stainless steel wire arranged in two triple staggered rows 31.0mm long, and has an integral knife blade which cuts between the triple rows. The staple leg length is 2.5mm before closure, and the the staple height is approximately 1.0mm when closed.

STERILE/SINGLE USE

Unless opened or damaged, contents of each package sterile,

DO NOT RESTERILIZE

CAUTION: Federal (U.S.A.) law restricts this device to sale, distribution, and use by, or on, the order of a physician.

Manufactured by United States Surgical Corporation
Norwalk, Connecticut 06856

*Trademark name not yet determined.

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DISPLAY BOX - SIDE PANELS

**Auto Suture®
ENDOSCOPIC GIA™-V Disposable Loading Unit***

Reorder Number

(Artwork)

Contains twelve disposable loading units.

**STERILE/SINGLE USE
DO NOT RESTERILIZE**

Unless opened or damaged, contents of each package sterile.

READ INFORMATION BOOKLET BEFORE USE

***Trademark name not yet determined.**

BEST AVAILABLE COPY

DISPLAY BOX - REAR PANEL

**Auto Suture®
ENDOSCOPIC GIA™-V Disposable Loading Unit***

Reorder Number

(Artwork)

For use with Auto Suture® ENDOSCOPIC GIA Surgical Stapler*

(BAR CODE)

LOT NUMBER:

EXP.:

***Trademark name not yet determined.**

BEST AVAILABLE COPY

INFORMATION BOOKLET FOR

**Auto Suture®
ENDOSCOPIC GIA™ Surgical Stapler*
and Disposable Loading Units**

(Artwork)

Important

This booklet is designed to assist in using the Auto Suture® ENDOSCOPIC GIA™ Surgical Stapler*. It is not a reference to endoscopic surgical stapling techniques. For information on surgical stapling techniques please see Endoscopy in Gynecology, J. M. Phillips, MD (Editor-in-Chief), Department of Publications, American Association of Gynecological Laparoscopists, Copyright 1978.

READ ALL INFORMATION CAREFULLY

CAUTION: Federal (U.S.A.) law restricts this device to sale, distribution, and use by, or on, the order of a physician.

*Trademark name not yet determined.

BEST AVAILABLE COPY

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**Auto Suture®
ENDOSCOPIC GIA™ Surgical Stapler*
and Disposable Loading Units**

Indications:

The Auto Suture® ENDOSCOPIC GIA™ Surgical Stapler* has application in endoscopic, gynecologic, and general abdominal procedures for the transection and resection of tissues.

Effects:

The ENDOSCOPIC GIA™ Surgical Stapler* places two triple staggered rows of stainless steel staples, and simultaneously divides the tissue between the two triple rows. The size of the staple is determined by the selection of the V or 3.5 disposable loading unit.

Schematic View and Nomenclature

**Auto Suture® ENDOSCOPIC GIA™ Surgical Stapler*
and Disposable Loading Unit**

(Artwork)

*Trademark name not yet determined.

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Instructions for Use

Auto Suture®

ENDOSCOPIC GIA™ Surgical Stapling Instrument*

1. Snap the disposable loading unit into the instrument by inserting the gray shaft into the collar located at the distal portion of the instrument. An audible click will signify complete seating of the disposable loading unit.

(Artwork)

2. With the disposable loading unit forks closed (the instrument clamping lever is flush against the body of the stapler), gently introduce the stapler through the trocar sleeve.

(Artwork)

2. Open the loading unit forks by opening the clamping lever of the surgical stapler. Place the loading unit forks across the tissue to be transected, or insert the forks into the lumen of the structure to be anastomosed.

(Artwork)

3. Close the clamping lever completely. An audible click will signify that the stapler is properly closed. Inspect the tissue for desired position within the cartridge forks. If necessary, open the clamping lever, reposition the tissue, and close the clamping lever again before firing the surgical stapler.

(Artwork)

*Trademark name not yet determined.

BEST AVAILABLE COPY

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4. To fire the surgical stapler, place thumb on the plunger located at the proximal end of the instrument. Compress the plunger as far as it will go (until flush with the instrument body), and then release.

Note: Do not use the ENDOSCOPIC GIA™ Surgical Stapler* on structures which cannot be visually inspected for hemostasis after application.

(Artwork)

5. Open the instrument clamping lever to release the tissue from the cartridge forks. Gently remove the instrument from the trocar sleeve. Always inspect the staple lines for hemostasis.

(Artwork)

6. Remove the expended disposable loading unit by grasping the grey shaft distal to the instrument collar and firmly pulling the loading unit out of the instrument. Discard. Never reuse the disposable loading units.

*Trademark name not yet determined.

BEST AVAILABLE COPY

**ENDOSCOPIC GIA™ Surgical Stapler*
Disposable Loading Unit Information**

ENDOSCOPIC GIA™-V Loading Unit*

The disposable loading unit contains 46 staples of 0.21mm diameter stainless steel wire arranged in two triple staggered rows 31.0mm long. The two sets of staple lines are approximately 3.0mm apart. An integral knife blade divides the tissue between the two triple rows of staples. The knife cut will end approximately 5mm short of the distal end of the staple rows. The staple leg length is 2.5mm before closure, and the staple height is approximately 1.0mm when closed. The preformed staple leg is a specific length; however, the height and shape of the closed staple may vary according to tissue thickness.

(Artwork)

ENDOSCOPIC GIA™-3.5 Loading Unit*

The disposable loading unit contains 34 staples of 0.23mm diameter stainless steel wire arranged in two triple staggered rows 31.0mm long. The two sets of staple lines are approximately 3.5mm apart. An integral knife blade divides the tissue between the two triple rows of staples. The knife cut will end approximately 5mm short of the distal end of the staple rows. The staple leg length is 3.5mm before closure, and the staple height is approximately 1.5mm when closed. The preformed staple leg is a specific length; however, the height and shape of the closed staple may vary according to tissue thickness.

(Artwork)

*Trademark name not yet determined.

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CAUTIONS AND CONTRAINDICATIONS

Cautions:

1. Make sure the loading unit forks of the ENDOSCOPIC GIA™ Surgical Stapler* are closed before introducing the instrument through a trocar sleeve.
2. Prior to firing, the instrument clamping lever must be completely closed against the instrument body (listen for audible click).
3. When applying the ENDOSCOPIC GIA™ Surgical Stapler* across tissue or into the lumen of organs to be anastomosed, make certain that the tissue is properly positioned and aligned in the forks of the loading unit, and that no extraneous tissue has been incorporated. Tissue should not extend below the "3cm" mark at the proximal end of the loading unit forks.
4. After firing, always inspect the staple lines for hemostasis. Minor bleeding may be controlled by means of electrocautery or by manual suture.
5. Discard the disposable loading unit immediately after use. Never reuse the disposable loading unit.
6. Endoscopic procedures should be performed only by persons having adequate training and familiarity with endoscopic techniques. Consult the medical literature relative to techniques, complications and hazards, prior to performance of any endoscopic procedure.
7. When endoscopic instruments and accessories from different manufacturers are employed together in a procedure, verify their compatibility, and ensure that electrical isolation or grounding is not compromised.
8. A thorough understanding of the principles and techniques involved in laser laparoscopy and electrosurgical procedures is essential to avoid shock and burn hazards to both the patient and operator(s), and damage to the instruments.

READ ALL INSTRUCTIONS CAREFULLY.

*Trademark name not yet determined.

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Contraindications:

1. Do not use the V size loading unit on any tissue that compresses to less than 1.0mm in thickness. In such cases, the staple may not be tight enough to ensure hemostasis.
2. Do not use the V size loading unit on any tissue which cannot compress comfortably to 1.0mm in thickness. In such cases the tissue is too thick for the staple size. However, the 3.5 staple size may be used.
3. Do not use the 3.5 size loading unit on any tissue that compresses to less than 1.5mm in thickness. In such cases, the staple may not be tight enough to ensure hemostasis. However, the V staple size may be used.
4. Do not use the 3.5 size loading unit on any tissue which cannot compress comfortably to 1.5mm in thickness. In such cases the tissue is too thick for the staple size.
5. The stapler should not be used on tissue such as liver or spleen, where compressibility is such that closure of the loading unit forks would be destructive.
6. Do not use the stapler where adequacy of hemostasis cannot be verified visually after application.

*Trademark name not yet determined.

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Method for Cleaning

Auto Suture® ENDOSCOPIC GIA Surgical Stapler*

DO NOT ATTEMPT TO DISASSEMBLE THE STAINLESS STEEL INSTRUMENT.

The ENDOSCOPIC GIA™ Surgical Stapling Instrument* may be cleaned with instrument cleaner like any other stainless steel instruments. For best results in maintaining Auto Suture® instruments, the use of Tomac™ Instrument Lubricant is recommended after each cleaning.

Sterilization:

Auto Suture® ENDOSCOPIC GIA™ Surgical Stapler* disposable loading units are supplied sterile, and intended for single use only. Discard after use. DO NOT RESTERILIZE. DO NOT EXPOSE TO TEMPERATURES ABOVE 130°F.

Manufactured by:

UNITED STATES SURGICAL CORPORATION

Norwalk, Connecticut 06856 Made in USA

*Trademark name not yet determined.

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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)
1390 Piccard Drive
Rockville, Maryland 20850

FEBRUARY 6, 1990

UNITED STATES SURGICAL CORP.
ATTN: CURTIS RAYMOND
150 GLOVER AVENUE
NORWALK, CT 06856

D.C. Number: K900129
Product : MODIFIED AUTO
SUTURE ENDOSCOPIC
GIA SURG. STAPLER*

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. This information and all correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

When your additional information is received by the Office of Device Evaluation Document Mail Center (address above), the 90-day period will begin again.

If after 30 days the requested information is not received, we will stop reviewing your submission and proceed to withdraw your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and the 90-day time period will begin again.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

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DO NOT REMOVE THIS ROUTE SLIP!!!!

K-90-0129

2/6/90

FROM: UNITED STATES SURGICAL CORP. ATTN: CURTIS RAYMOND 150 GLOVER AVENUE NORWALK, CT 06856		LETTER DATE 12/29/89	LOGIN DATE 01/03/90	DUE DATE 04/03/90
SHORT NAME: UNITSTATSURG		ESTABLISHMENT NO:		CONTROL # K900129
TO: ODE/DMC		CONT. CONF.: ? STATUS : H REV PANEL : SU PAN/PROD CODE(S): SU/ / /		
SUBJECT: MODIFIED AUTO SUTURE ENDOSCOPIC GIA SURG. STAPLER*				
DECISION: DECISION DATE: / /	RQST INFO DATE: 02/06/90	INFO DUE DATE: 03/08/90		
	DATE: / /	DATE: / /		
	DATE: / /	DATE: / /		
	DATE: / /	DATE: / /		
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

2/6/90

From REVIEWER(S) - NAME(S) RM Noelund

Subject 510(k) NOTIFICATION H900129

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Additional Comments:

*see attached memo
2/6/90*

The submitter requests under 21 CFR §807.95:

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code w/Panel and class:

ADW - Class II

Additional Product Code(s) w/Panel (optional):

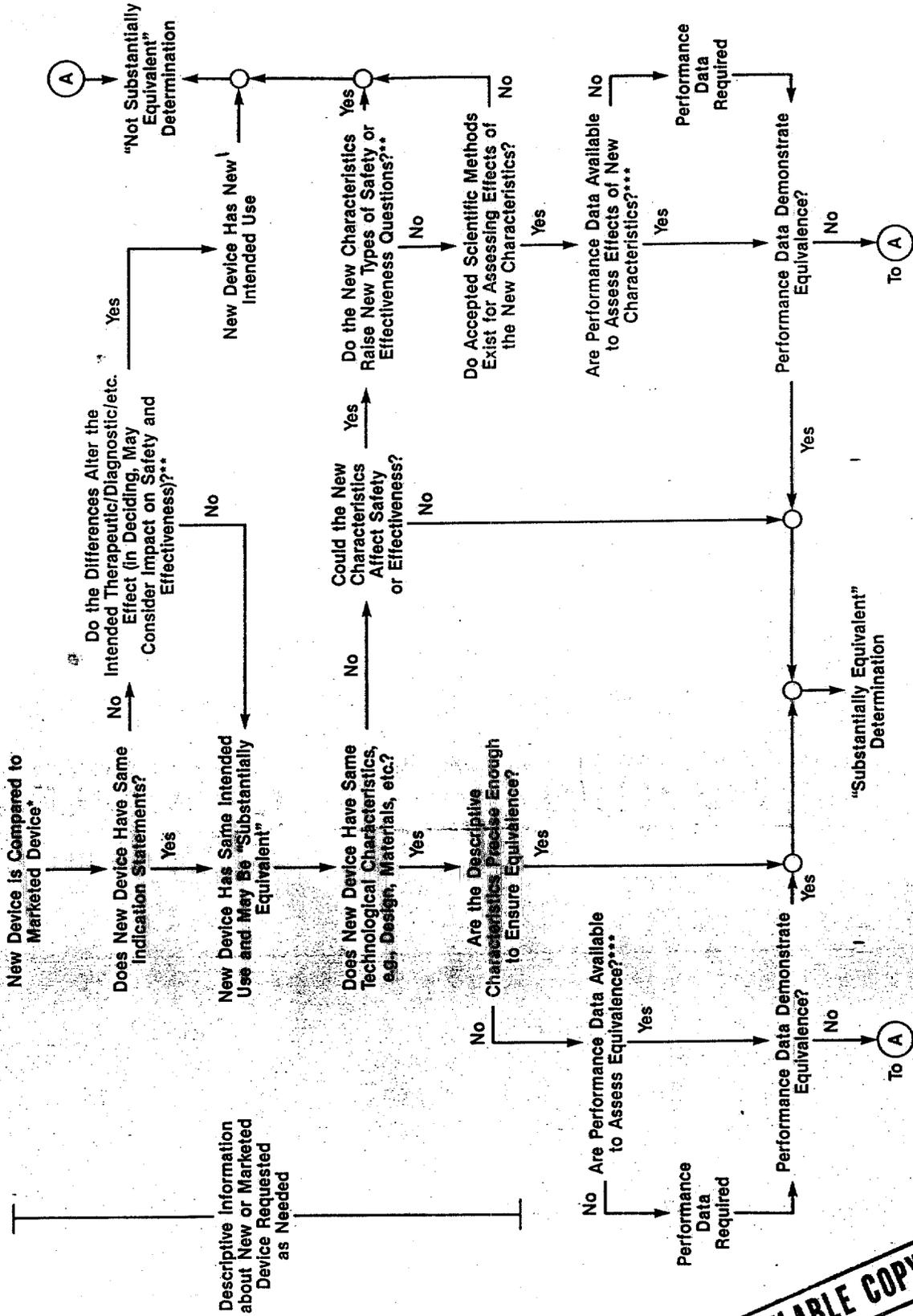
REVIEW: _____ (DATE)
(BRANCH CHIEF)

FINAL REVIEW: _____ (DATE)
(DIVISION DIRECTOR)

*X
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510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



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** This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.
 *** Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (pre-Amendments or Reclassified Post-Amendments) Devices is Unclear.

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MEMO TO THE RECORD

DATE: 2/6/90
FROM: BIOLOGIST

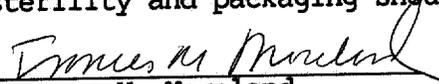
OFFICE: HFZ-410
DIVISION: DSRD/SDB

RE: K900129, Modified Auto Suture Endoscopic GIA Surgical Stapler

CONTACT: Curtis Raymond

PHONE: (203)
866-5050

USSC has submitted a request for "amending" their 510(k) for this device. They wish to make the device totally disposable and also to include an additional staple size for the device. This is regarded as a significant device change and for this reason, a 510(k) will be required (an "amendment" is not acceptable nor possible). The sponsor is to be reminded of the 510(k) process and informed that a full 510(k) will be required. The information as submitted is complete, with the exception of lack of complete labeling. The sponsor will be informed that he needs to supply this. There is no difficulty in permitting the marketing of an additional staple size (since this size is already on the market in another USSC device (TA* 30 Premium 3.5 surgical stapler). The sponsor is also to be advised that a more detailed statement for the issues of sterility and packaging should also be included.



Frances M. Moreland
Division of Surgical and
Rehabilitation Devices

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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)
1390 Piccard Drive
Rockville, Maryland 20850

JANUARY 10, 1990

UNITED STATES SURGICAL CORP.
ATTN: CURTIS RAYMOND
150 GLOVER AVENUE
NORWALK, CT 06856

D.C. Number : K900129
Received : 01-03-90
90th Day : 04-03-90
Product : MODIFIED AUTO
SUTURE ENDOSCOPIC
GIA SURG. STAPLER*

The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug, and Cosmetic Act for the above referenced device has been received and assigned an unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

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FHM



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date 1/3/90

K900129

To Jessica S. Lewis, Clerk-Typist (CDRH, ODE, DMC) HFZ-401

Subject Premarket Notification Number(s) K892233

To Division Director Su

The attached information has been received by 510(k) Document Mail Center (DMC), on the above referenced 510(k) file(s). Since a final decision has been rendered, the record is officially closed.

Please review the document(s) and return to DMC directed to my attention, with one of the statements checked below. Feel free to note any additional comments below. If there are any questions, please contact me on 427-1027. Thank you for your cooperation.

Information does not change status of 510(k); no other action required by DMC; please file. The Division should prepare a confirmation letter - example attached.

X Additional information requires a new 510(k); please process.

COMMENTS: See attached memo 1/10/90 Frances M. Moreland

This information should be returned by 1/15/90

Reviewed by: F.M. Moreland

Panel: SPS Date: 1/10/90

1/10/90

R M Moreland

Subject: USSC request for modification to previously SE 510(k) for device K892233, Auto Suture Endoscopic GIASurgical Stapler*

The sponsor has provided additional information to the agency relating to the above mention device that was previously found to be SE to currently marketed devices. The proposed device modifications are as follows:

1. the change of stapling device from that of a reusable device to a disposable type of device; and,
2. a change in the closure length of the staple from 1.0mm to that of 1.5 mm, to accomodate tissue that would have a slightly larger tissue compression requirement.

The sponsor has stated that the method of sterilization, device manufacture, indications for use, method of use, labeling, and device compositional materials would not change. However, it is my opinion that the device design has significantly changed, i.e., the size of the staple as well as the change from reusable stapler to that of a stapler that is nondisposable in nature, and for these two reasons I recommend that the sponsor be required to submit a new 510(k) for this device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

Re: Device Name
Dated:
Received:

Dear _____:

We have reviewed the information dated _____, regarding the 510(k) notification (K _____) previously submitted for the device referenced above. Based solely on the information that you have provided, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). The information you have supplied will be added to the file.

If you have any questions regarding the contents of this letter, please contact _____ at (301) 427-_____.

Sincerely yours,

Division Director
Division of _____
Office of Device Evaluation
Center for Devices and
Radiological Health

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K900129

United States Surgical Corporation

150 Glover Avenue, Norwalk, Connecticut 06856 (203) 865-5050

FDA-CDRH-OCE

JAN 3 1990

DOCUMENT MAIL CENTER

December 29, 1989

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

ATTN: Division of Surgical and Rehabilitation Devices (HFZ-410)

Reference: 510(k) Notification No. **K892233**
Auto Suture® Endoscopic GIA™ Surgical Stapler*

Gentlemen/Ladies:

With regard to the above referenced premarket notification for the Auto Suture® Endoscopic GIA™ Surgical Stapler*, United States Surgical Corporation (Establishment Registration Number 1219161) wishes at this time to advise the Agency of modifications to the subject device.

As described in 510(k) Notification No. K892233, submitted on March 31, 1989, the subject device consists of a reusable stainless steel instrument to which is fitted a sterile, single-use disposable loading unit (d.l.u.) containing two triple-staggered rows of fine stainless steel staples and an integral knife blade. The device is designed to perform secure and hemostatic division of soft tissues endoscopically when introduced through a standard trocar sleeve of 10mm or larger diameter, and has application in endoscopic, gynecological, and general abdominal procedures for the transection and resection of tissues.

The modifications to the device which are the subject of this letter are twofold: First, the manufacture of a wholly disposable instrument having an integral loading unit, and second, manufacture of the device with a slightly larger staple to accommodate thicker tissues. In no other manner will the device differ from that which was described in 510(k) Notification No. K892233.

* Trademark name not yet determined.

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For over twenty years, United States Surgical Corporation has marketed a wide array of surgical stapling devices for use in a variety of surgical applications. One of the first such instruments is the pre-amendment Auto Suture® GIA™ surgical stapler. Originally marketed in 1967, it is a reuseable stainless steel device to which are affixed sterile, single-use disposable loading units (d.l.u.) containing fine stainless steel staples. This and other Auto Suture® devices were later offered in sterile, totally disposable forms having integrated instrument and d.l.u. components. These GIA™ instruments, like the preamendment TA® surgical staplers, offer a range of staple sizes to accomodate varying thicknesses of tissue.

In recent years, United States Surgical Corporation has introduced a series of endoscopic surgical devices to address the increasing use of endoscopic surgical procedures. Among these devices are the Auto Suture® SURGIPORT™ disposable surgical trocar (Reference 510[k] nos. K862611 and K874879), and the Auto Suture® ENDO CLIP™ Surgical Clip Applier (Reference 510[k] nos. K883018 and K890941).

This latter device was originally marketed only as a wholly integrated, sterile, disposable instrument, but as is the case with the majority of Auto Suture® clip and staple devices, it is now offered in both the disposable form, and in a two-part version consisting of a reuseable stainless steel instrument to which is affixed a sterile disposable loading unit containing the ligating clips.

United States Surgical Corporation wishes at this time to provide the same options relative to the subject Endoscopic GIA™ Surgical Stapler*, by marketing a wholly integrated, sterile, surgical stapler in addition to the currently marketed two-part device consisting of a reusable stainless steel instrument and a sterile d.l.u. As is the case with other totally disposable forms of Auto Suture® surgical instruments, the integral cartridge portion of the disposable form of the subject device is identical to the d.l.u. employed with the current reusable instrument, having been manufactured in the same fashion from the same materials, having the same staples, and operating in the same manner using the same mechanisms. This modification does not affect intended use, nor does it affect method of use beyond eliminating d.l.u.-loading prior to application, and steel instrument cleaning and maintenance requirements.

The second modification is that of manufacturing the subject device with a larger size staple, thereby providing the physician a choice of two staple sizes to accomodate different tissue thicknesses. The availability of a range of staple sizes has long been common to all Auto Suture® GIA™ and TA® surgical stapling instruments, and exclusive of the staple size difference, in no way does it affect the design, materials, method of use, or intended use of these instruments. Such is also the case with the subject device.

* Trademark name not yet determined.

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The current Endoscopic GIA™ Surgical Stapler* contains 46 staples of 0.21mm diameter (b) (4) stainless steel wire arranged in two triple staggered rows approximately 31.0mm in length. Each staple measures 3.0mm across the backspan, and the staple leg length is 2.5mm. The staple height is approximately 1.0mm when closed. As described in 510(k) no. K892233 for the subject device, the staples and the staple row length are identical to that created by the Auto Suture® TA® 30 PREMIUM® V3 surgical stapler, and are designed to accommodate tissue which can compress comfortably to approximately 1.0mm in thickness.

United States Surgical Corporation now wishes to make available the same device having a larger staple identical to that contained in the Auto Suture® TA® 30 PREMIUM® 3.5 surgical stapler. Such staple is composed of 0.23mm diameter (b) (4) stainless steel wire, measuring 4.0mm across the backspan, and with a staple leg length of 3.5mm before closure. The staple height is approximately 1.5mm when closed, and is designed to accommodate tissues which can compress comfortably to approximately 1.5mm in thickness. Beyond this difference, however, the modification in no way affects the design, materials, method of use, or intended use of the subject device. Figure I depicts a dimensional comparison between the 2.5mm-long staples currently employed in both the TA® 30 PREMIUM® V3 and the subject device, and the 3.5mm-long staples currently employed in the TA® 30 PREMIUM® 3.5 instrument, and which are proposed for use in the subject device.

In summary, the modified Endoscopic GIA™ Surgical Stapler* differs from that described in 510(k) Notification No. K892233 only in that:

The two-part form consisting of a reuseable stainless steel instrument to which is affixed a single-use, sterile, loading unit containing the staples is now manufactured as a totally disposable, sterile, single-use instrument, wherein the loading unit containing the staples is an integral part of the device.

The device will now be offered with an additional staple size corresponding to that long-utilized in the TA® 30 PREMIUM® 3.5 surgical staplers, and designed to accommodate tissues which can compress comfortably to approximately 1.5mm in thickness.

Labeling changes reflecting these modifications will consist solely of the elimination of d.l.u.-loading and instrument cleaning and maintenance instructions, and addition of a schematic description of the larger staple size now available (see Figure I). Exclusive of these differences, the modified Endoscopic GIA™ Surgical Stapler* described herein remains unchanged from that described in the previous 510(k) submission, no. K892233, in that:

* Trademark name not yet determined.

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There is no change in intended use.

There is no change in method of use.

There is no change in staple material or method of closure.

There is no change in materials or manufacturing methods. The totally disposable instrument is manufactured using the same materials and methods as are employed to manufacture the current form of the device, as well as numerous other Auto Suture® disposable surgical staplers.

There is no change in principles or mechanisms of operation. The integral cartridge portion of the totally disposable instrument is identical to the single-use d.l.u. employed in the currently-marketed device.

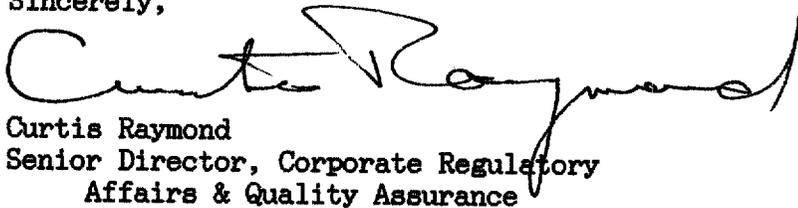
There is no change in packaging materials or methods.

There is no change in sterilization, in that the single-use totally disposable instrument is sterilized in the same manner, and the sterilization monitored in the same manner, as the single use d.l.u. portion of the currently marketed device.

It is the position of United States Surgical Corporation that its intention to market the modified device described herein constitutes confidential commercial information. The intention to market this device has not been disclosed to persons outside the Company except technical consultants/suppliers to United States Surgical Corporation. Consequently, we hereby request that the Agency maintain the confidentiality of this matter until such time as permission to market is granted.

We trust the enclosed information will prove sufficient for the notification purposes.

Sincerely,


Curtis Raymond
Senior Director, Corporate Regulatory
Affairs & Quality Assurance

* Trademark name not yet determined.

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2.5mm staple and staple line configuration



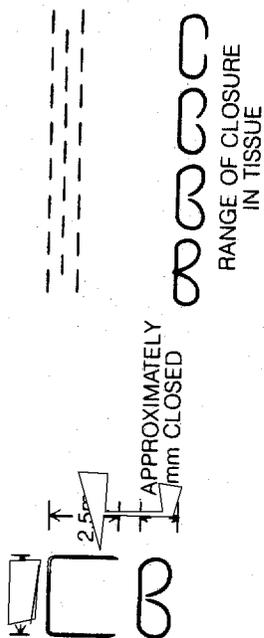
Endoscopic GIA™ Surgical Stapler
510(k) K892233

3.5mm staple and staple line configuration



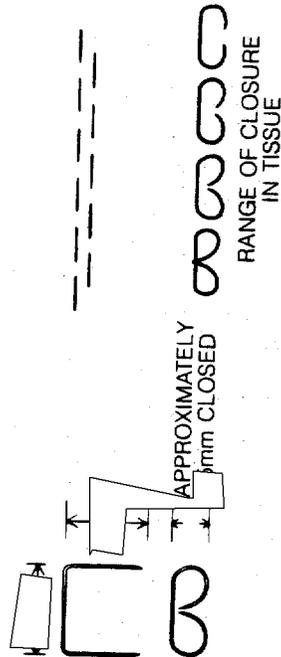
MODIFIED
Endoscopic GIA™ Surgical Stapler

2.5mm staple and staple line configuration



Auto Suture® TA® 30 PREMIUM® V3
Surgical Stapler

3.5mm staple and staple line configuration



Auto Suture® TA® 30 PREMIUM® 3.5
Surgical Stapler

FIGURE 1

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