



U.S. Department of Health & Human Services

Food and Drug Administration

FOIA RESPONSE

USER: (ixg)
FOLDER: K033269 - 82 pages (FOI:10006766)
COMPANY: ()
PRODUCT: ENDOSCOPE AND/OR ACCESSORIES (KOG)
SUMMARY: Product: ENDOPATH ENDOCUTTER GRAY CARTRIDGE, MODEL 6R45M/GRAY CARTRIDGE RELOAD
DATE REQUESTED: Mar 25, 2011
DATE PRINTED: Apr 4, 2011
Note: Releasable Version



510(k) Summary of Safety and Effectiveness Information

Company Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242

Contact Georgia C. Abernathy, MBA, RAC
Senior Regulatory Affairs Associate
Telephone: (513) 337-3179
Fax: (513) 337-1444
Email: gabernat@eesus.jnj.com

Date Prepared October 8, 2003

Device Name Trade Name: ENDOPATH® Endocutter Gray Cartridge
Classification Name: Endoscope and Accessories, Implantable Staples

Predicate Device ENDOPATH® Linear Cutters and Staplers

Device Description These instruments are all mechanical surgical stapling devices. The ENDOPATH Linear Cutter models are sterile single use instruments that deliver staples while simultaneously dividing tissue between rows. The ENDOPATH No-Knife Staplers are sterile single use instruments that deliver staples, but do not cut. These instruments may be used in either open or Endoscopic procedures, depending upon the design. Some instruments are Reloadable and, if so, they may be reloaded with various reloads (i.e., vascular/thin, standard, thick) depending on the thickness of tissue that is to be transected or resected.

Indications for Use

The ENDOPATH ETS45 Endoscopic Linear Cutters, the ETS-Flex45 Endoscopic Articulating Linear Cutters, and the ETS Compact-Flex45 Articulating Linear Cutters are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

The ENDOPATH ETS-Flex-45 No-Knife Articulating Linear Staplers and the ETS Compact-Flex45 No-Knife Articulating Linear Staplers are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

Technological Characteristics This is an addition of a gray cartridge reload to this product line. The Gray Cartridge is for use on thin tissue such as mesentery and vessels and has a nominal closed staple height of 0.85mm.

Performance Data Bench testing and pre-clinical laboratory evaluations were performed to demonstrate that the device will perform as intended.



DEC 10 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Georgia C. Abernathy, MBA, RAC
Senior Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K033269
Trade/Device Name: ENDOPATH® Endocutter Gray Cartridge
Regulation Number: 21 CFR 876.1500, 878.4750
Regulation Name: Endoscope and accessories, implantable staple
Regulatory Class: II
Product Code: KOG, GDW
Dated: October 8, 2003
Received: October 16, 2003

Dear Ms. Abernathy:

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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
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): K033269

Device Name: ENDOPATH® Endocutter Gray Cartridge

Indications For Use:

The ENDOPATH ETS45 Endoscopic Linear Cutters, the ETS-Flex45 Endoscopic Articulating Linear Cutters, and the ETS Compact-Flex45 Articulating Linear Cutters are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

The ENDOPATH ETS-Flex45 No-Knife Articulating Linear Staplers and the ETS Compact-Flex45 No-Knife Articulating Linear Staplers are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

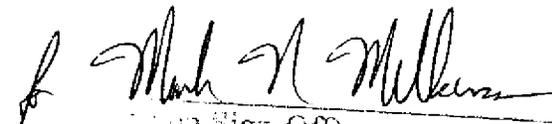
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


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

Page 1 of 1

510(k) Number K033269

Document Cover Sheet:

K033269-K4659

FSR0203-000

Date of Submission:	08-OCT-2003
Description:	ENDOPATH ENDOCUTTER GRAY CARTRIDGE, MODEL 6R45M/GRAY CARTRID
Date of Scan:	05-JAN-2004
Document Prep:	NXC4 05-01-04
Scanner:	NXC4 05-01-04
Image Quality Reviewer:	NBB 09-01-04



Document Expected	Page # Start	Page # End	Page In Doc	Indexer
Decision Letter 10-DEC-2003	1	2	3	<input checked="" type="checkbox"/>
Indications for Use 10-DEC-2003	3	3	2	<input checked="" type="checkbox"/>
Reviewer Memorandum	4	4	2	<input checked="" type="checkbox"/>
510K Decision Tree	5	5	2	<input checked="" type="checkbox"/>
Reviewer Notes	6	11	7	<input checked="" type="checkbox"/>
Acknowledgement Letter 17-OCT-2003	12	14	4	<input checked="" type="checkbox"/>
Original 08-OCT-2003	15	74	61	<input checked="" type="checkbox"/>
Cover Letter 08-OCT-2003	15	15	2	<input checked="" type="checkbox"/>
Contents 08-OCT-2003	16	74	60	<input checked="" type="checkbox"/>
Total documents: 7				<input type="checkbox"/>
Total document pages: 74				<input checked="" type="checkbox"/>
Total separator pages: 8				<input type="checkbox"/>
Total Scan pages: 83				<input type="checkbox"/>

Document Expected	Page # Start	Page # End	Page In Doc	Indexer
QC Signature	SNC	09-JAN-04	QC Bar Code Sticker	

Document Cover Sheet:

K033269-K4659

FSR0203-000

Date of Submission:	08-OCT-2003
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Image Quality Reviewer:	



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510K Decision Tree	5	5	2	<input type="checkbox"/>
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Total document pages: 74				<input type="checkbox"/>
Total separator pages: 8				<input type="checkbox"/>
Total Scan pages: 83				<input type="checkbox"/>

Document Expected	Page # Start	Page # End	Page In Doc	Indexer
QC Signature			QC Bar Code Sticker	



DEC 10 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Georgia C. Abernathy, MBA, RAC
Senior Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K033269
Trade/Device Name: ENDOPATH® Endocutter Gray Cartridge
Regulation Number: 21 CFR 876.1500, 878.4750
Regulation Name: Endoscope and accessories, implantable staple
Regulatory Class: II
Product Code: KOG, GDW
Dated: October 8, 2003
Received: October 16, 2003

Dear Ms. Abernathy:

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.

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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 (301) 594-4659. 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
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): K033269

Device Name: ENDOPATH® Endocutter Gray Cartridge

Indications For Use:

The ENDOPATH ETS45 Endoscopic Linear Cutters, the ETS-Flex45 Endoscopic Articulating Linear Cutters, and the ETS Compact-Flex45 Articulating Linear Cutters are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

The ENDOPATH ETS-Flex45 No-Knife Articulating Linear Staplers and the ETS Compact-Flex45 No-Knife Articulating Linear Staplers are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


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

Page 1 of 1

510(k) Number K033269

October 17, 2003

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

ETHICON ENDO-SURGERY, INC.
4545 CREEK RD.
CINCINNATI, OH 45242
ATTN: GEORGIA C. ABERNATHY

510(k) Number: K033269
Received: 16-OCT-2003
Product: ENDOPATH ENDOCUTTER
GRAY CARTRIDGE,
MODEL 6R45M/GRAY
CARTRIDGE RELOAD

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 any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at <http://www.fda.gov/oc/mdufma>).

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 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.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,

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

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

October 09, 2003

ETHICON ENDO-SURGERY, INC.
4545 CREEK RD.
CINCINNATI, OH 45242
ATTN: GEORGIA C. ABERNATHY

510(k) Number: K033269
Received: 09-OCT-2003
Product: ENDOPATH ENDOCUTTER
User Fee ID Number: CARTRIDGE,
MODEL 6R45M/GRAY

The Food and Drug Administration (FDA) Center for Devices and Radiological Heath (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 any 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. The payment information we need in order to begin the review of your 510(k) includes, the user fees cover sheet with the payment ID faxed to the Office of Financial Management at (301) 827-9213 and a check mailed to:

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 also be faxed to CDRH at (301) 594-2977 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 <http://www.fda.gov/oc/mdufma>.

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 an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-free number (800)638-2041, or contact them at their Internet address <http://www.fda.gov/cdrh/dsmamain.html>, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

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



K033269

4545 CREEK ROAD
CINCINNATI, OH 45242-2839

October 8, 2003

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of General and Plastic Surgery Devices
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

RECEIVED
2003 OCT -9 P 2: 34
FDA/CDRH/CDER/OPMD

Re: **Traditional 510(k) Premarket Notification**
ENDOPATH® Endocutter Gray Cartridge
Addition of a 6-row Gray Cartridge Reload - Line Extension

Dear Sir or Madam:

Pursuant to 21 CFR 807.90, Ethicon Endo-Surgery, Inc. is submitting two copies of this 510(k) notification for ENDOPATH Endocutter Gray Cartridge and two copies of this cover letter. This Premarket Notification is being submitted as notification of Ethicon Endo-Surgery, Inc.'s intent to market an addition of a smaller height (0.85mm) 6 row staple reload to the 45mm product line. This modification is to be called the ENDOPATH Endocutter Gray Cartridge.

Labeling will be updated to reflect a new contraindication for tissue compression range associated with the new staple dimensions.

All information necessary for a substantial equivalence determination is included herein.

If you have any questions about this notification, please contact me at:

Phone - (513) 337-3179
Fax - (513) 337-1444

Or contact Dennis Hahn, Director of Regulatory Affairs at:

Phone - (513) 337-3134
Fax - (513) 337-1444.

Sincerely,

Georgia C. Abernathy, MBA, RAC
Senior Regulatory Affairs Associate

Enclosure

15
SKDF
SU
II

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* An extra copy in a plastic sleeve is included for reviewer convenience.

Section A

CDRH Submission Cover Sheet

The CDRH Submission Cover Sheet for the proposed device is provided on the following pages.

CDRH Submission Cover Sheet

CDRH SUBMISSION COVER SHEET				
Date of Submission: October 8, 2003			FDA Document Number:	
Section A Type of Submission				
PMA <input type="checkbox"/> Original submission <input type="checkbox"/> Modular submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	PMA Supplement <input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30 day-Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA Supplement	PDP <input type="checkbox"/> Presubmission summary <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of intent to start clinical trails <input type="checkbox"/> Intention to submit Notice of Completion <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP <input type="checkbox"/> Report	510(k) <input checked="" type="checkbox"/> Original submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input type="checkbox"/> Additional information: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	Meeting <input type="checkbox"/> Pre-IDE meeting <input type="checkbox"/> Pre-PMA meeting <input type="checkbox"/> Pre-PDP meeting <input type="checkbox"/> 180-day meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption <input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report	Class II exemption <input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	Evaluation of Automatic Class III Designation <input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	Other Submission Describe submission:
Section B Applicant or Sponsor				
Company / Institution name: Ethicon Endo-Surgery, Inc.			Establishment registration number: 1527736	
Division name (if applicable):			Phone number (include area code): 513-337-3179	
Street address: 4545 Creek Road			FAX number (include area code): 513-337-1444	
City Cincinnati	State / Province: OH		Country USA	
Contact name: Georgia C. Abernathy, MBA, RAC				
Contact title: Senior Regulatory Affairs Associate			Contact e-mail address: gabernat@eesus.jnj.com	
Section C Submission correspondent (if different from above)				
Company / Institution name:			Establishment registration number:	
Division name (if applicable):			Phone number (include area code): ()	
Street address			FAX number (include area code): ()	
City	State / Province:			
Contact name:				
Contact title:			Contact e-mail address:	

Section D1	Reason for Submission - PMA, PDP, or IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or expanded indications <input type="checkbox"/> Licensing agreement <input type="checkbox"/> Process change <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Response to FDA correspondence <input type="checkbox"/> Request for applicant hold <input type="checkbox"/> Request for removal of applicant hold <input type="checkbox"/> Request for extension <input type="checkbox"/> Request to remove or add manufacturing site <input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf life <input type="checkbox"/> Trade name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager <input type="checkbox"/> Distributor <input type="checkbox"/> Report submission: <input type="checkbox"/> Annual or periodic <input type="checkbox"/> Post-approval study <input type="checkbox"/> Adverse reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment <input type="checkbox"/> Change in ownership <input type="checkbox"/> Change in correspondent	
Section D2	Reason for Submission - IDE		
<input type="checkbox"/> New device <input type="checkbox"/> Addition of institution <input type="checkbox"/> Expansion / extension of study <input type="checkbox"/> IRB certification <input type="checkbox"/> Request hearing <input type="checkbox"/> Request waiver <input type="checkbox"/> Termination of study <input type="checkbox"/> Withdrawal of application <input type="checkbox"/> Unanticipated adverse effect <input type="checkbox"/> Notification of emergency use <input type="checkbox"/> Compassionate use request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continuing availability request <input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent <input type="checkbox"/> Design <input type="checkbox"/> Informed consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturer Process <input type="checkbox"/> Protocol - feasibility <input type="checkbox"/> Protocol - other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current investigator <input type="checkbox"/> Annual progress <input type="checkbox"/> Site waiver limit reached <input type="checkbox"/> Final	<input type="checkbox"/> Response to FDA letter concerning: <input type="checkbox"/> Conditional approval <input type="checkbox"/> Deemed approved <input type="checkbox"/> Deficient final report <input type="checkbox"/> Deficient progress report <input type="checkbox"/> Deficient investigator report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request extension of time to respond to FDA <input type="checkbox"/> Request meeting	
Section D3	Reason for Submission - 510(k)		
<input type="checkbox"/> New device <input type="checkbox"/> Additional or expanded indications <input checked="" type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Change in technology <input type="checkbox"/> Change in design	<input type="checkbox"/> Change in materials <input type="checkbox"/> Change in manufacturing process	
<p>Add a smaller height (0.85mm) staple reload to the existing product line. Labeling revisions to product insert Contraindications section.</p>			

Section E Additional Information on 510(k) Submissions					
Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data: <input checked="" type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement	
1 GDW	2 KOG	3	4		
5	6	7	8		
Information on devices to which substantial equivalence is claimed:					
510(k) Number	Trade or proprietary or model name			Manufacturer	
1. K020779	Endopath & Proximate Linear Cutters & Staplers			Ethicon Endo-Surgery, Inc.	
2. K002398	Endopath ETS45 Linear Cutters, Staplers & Reloads Product Family			Ethicon Endo-Surgery, Inc.	
3. K980815	Endopath EZ45 Endoscopic Linear Cutter			Ethicon Endo-Surgery, Inc.	
4. K961390	Endopath ETS Endoscopic Linear Cutter and ETS-Flex Endoscopic /Articulating Linear Cutter Devices			Ethicon Endo-Surgery, Inc.	
5.					
6.					
Section F Product Information - Applicable to All Applications					
Common or usual name or classification name: Endoscope and Accessories (KOG); Implantable staple (GDW)					
Trade or proprietary or model name				Model number	
1. Endopath Endocutter Gray Cartridge				6R45M / Gray Cartridge Reload	
2.					
3.					
4.					
FDA document numbers of all prior related submissions (regardless of outcome):					
1 K020779	2 K002398	3 K980815	4 K980023	5 K961390	6 K935064
7	8	9	10	11	12
Data included in submission: <input checked="" type="checkbox"/> Laboratory testing <input checked="" type="checkbox"/> Animal trials <input type="checkbox"/> Human trials					
Section G Product Classification - Applicable to All Applications					
Product code: KOG, GDW	C.F.R. Section: 21 CFR 876.1500; 21 CFR 878.4750			Device class: <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified	
Classification panel: General and Plastic Surgery					
Indications (from labeling):					
<p>The ENDOPATH ETS45 Endoscopic Linear Cutters, the ETS-Flex45 Endoscopic Articulating Linear Cutters, and the ETS Compact-Flex45 Articulating Linear Cutters are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.</p> <p>The ENDOPATH ETS-Flex45 No-Knife Articulating Linear Staplers and the ETS Compact-Flex45 No-Knife Articulating Linear Staplers are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.</p>					

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number:	
Section II Manufacturing / Packaging / Sterilization Sites Relating to a Submission			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: 1527736		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Contract manufacturer <input type="checkbox"/> Repackage / relabeler
Company / Institution name: Ethicon Endo-Surgery, Inc.		Establishment registration number: 1527736	
Division name (if applicable): N/A		Phone number (include area code): (b)(4)	
Street address: 4545 Creek Road		FAX number (include area code): (513) 337-3071	
City: Cincinnati	State / Province: OH	Country: USA	
Contact Name: (b)(4)			
Contact title: Director, Quality Compliance Services		Contact e-mail address: (b)(4)	
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: 1628808		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Contract manufacturer <input type="checkbox"/> Repackager/ relabeler
Company / Institution name: Ethicon Endo-Surgery, Inc.		Establishment registration number: 1628808	
Division name (if applicable): N/A		Phone number (include area code): (b)(4)	
Street address: 3801 University Blvd. S.E.		FAX number (include area code): (505) 768-5260	
City: Albuquerque	State / Province: NM	Country: USA	
Contact Name: (b)(4)			
Contact title: Quality Systems Manager		Contact e-mail address: (b)(4)	
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: 9681530		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Contract manufacturer <input type="checkbox"/> Repackager/ relabeler
Company / Institution name: Ethicon Endo-Surgery, Inc. S.A. de C.V. Planta I		Establishment registration number: 9681530	
Division name (if applicable): N/A		Phone number (include area code): (b)(4)	
Street address: Ave. de Las Torres 7125, Col. Salvarcar		FAX number (include area code): (915) 791-3495	
City: Ciudad Juarez	State / Province: Chihuahua	Country: Mexico	
Contact Name: (b)(4)			
Contact title: Quality Systems Manager		Contact e-mail address: (b)(4)	

Section B

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

The Screening Checklist for all Premarket Notification [510(k)] Submissions for the proposed device is provided on the following pages.

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 |
| <input checked="" type="checkbox"/> Traditional 510(k) or no identification provided - | Do Sections 1 and 4 |

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

	Present	Inadequate or Missing
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.	Page 1	
Table of Contents.	Page 2	
Truthful and Accurate Statement.	Section C	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	Section A	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	Section A	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.	Section L	
Statement of Indications for Use that is on a separate page in the premarket submission.	Section D	
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.	Section J	
510(k) Summary or 510(k) Statement.	Section K	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	Section E	
Identification of legally marketed predicate device. *	Section A	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	Section G	
Class III Certification and Summary. **	N/A ¹	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	N/A ¹	
510(k) Kit Certification ***	N/A ¹	

¹ - N/A = Not Applicable

* - 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	Inadequate or Missing
Name and 510(k) number of the sponsor's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
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 sponsor's unmodified predicate device.		
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.		
A Design Control Activities Summary that includes the following elements (a-e):		
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.		
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.		
c. A Declaration of Conformity with design controls that includes the following statements:		
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.		
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.		

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

	Present	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.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, see <u>Required Elements for a Declaration of Conformity to a Recognized Standard</u> .		
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.		
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.		
For a submission, which relies on a non-recognized standard that has <u>not</u> 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 <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
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.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

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

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	Section F	
b) Sterilization and expiration dating information:	Section H	
i) sterilization process	Section H	
ii) validation method of sterilization process	Section H	
iii) SAL	Section H	
iv) packaging	Section H	
v) specify pyrogen free	N/A ¹	

vi) EtO residues	N/A ¹	
vii) radiation dose	Section H	
c) Software Documentation:	N/A ¹	

Items with checks in the "Missing" column must be submitted before substantive review of the document.

Passed Screening ____ Yes ____ No

Reviewer: _____

Concurrence by Review Branch: _____

Date: _____

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>

UPLOADED ON JANUARY 29, 2002

Section C

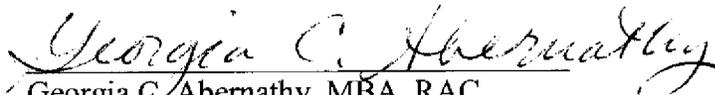
Premarket Notification Truthful and Accurate Statement

The Premarket Notification Truthful and Accurate Statement for the proposed device is provided on the following pages.

Premarket Notification Truthful and Accurate Statement

The Truthful and Accurate Statement, as required by 21 CFR 807.87(k) is provided below.

I certify that, in my capacity as Senior Regulatory Affairs Associate of Ethicon Endo-Surgery, Inc., I believe, to the best of my knowledge, that all data and information submitted to me in the premarket notification are truthful and accurate and that no material fact related to a substantial equivalence decision has been omitted.



Georgia C. Abernathy, MBA, RAC
Senior Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc.

October 8, 2003

Date

Section D

FDA Indications for Use Statement

The Indications for Use Statement for the proposed device is provided on the following page. An extra copy has been included in a plastic sleeve for reviewer convenience.

Indications for Use Statement

510 (k) Number (if known): _____

Device Name: **ENDOPATH® Endocutter Gray Cartridge**

Indications for Use:

The ENDOPATH ETS45 Endoscopic Linear Cutters, the ETS-Flex45 Endoscopic Articulating Linear Cutters, and the ETS Compact-Flex45 Articulating Linear Cutters are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

The ENDOPATH ETS-Flex45 No-Knife Articulating Linear Staplers and the ETS Compact-Flex45 No-Knife Articulating Linear Staplers are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Section E

Device Description

Device Design and Principles of Operation

The ENDOPATH Linear Cutter models are sterile single use instruments that deliver staples while simultaneously dividing tissue between rows. The ENDOPATH No-Knife Staplers are sterile single use instruments that deliver staples, but do not cut. Depending upon the particular model, they deliver 2 to 3 staggered rows of staples, 2 double-staggered rows, or 2 triple-staggered rows of staples. Staple line lengths vary between 35mm and 100mm. These instruments may be used in either open or Endoscopic procedures, depending upon the design. Some instruments are Reloadable and, if so, they may be reloaded with various reloads (i.e., vascular/thin, standard, thick) depending on the thickness of tissue that is to be transected or resected. Vascular models use specific vascular reload cartridges. The instruments may be reloaded a number of times according to product insert instructions for a maximum number of firings per instrument. Some instruments have articulating heads and flex features. The length of the shaft may vary as well. A safety lockout feature on linear cutter instruments prevents a used reload from being fired again. The common element among all these instruments is that they are all mechanical surgical stapling devices.

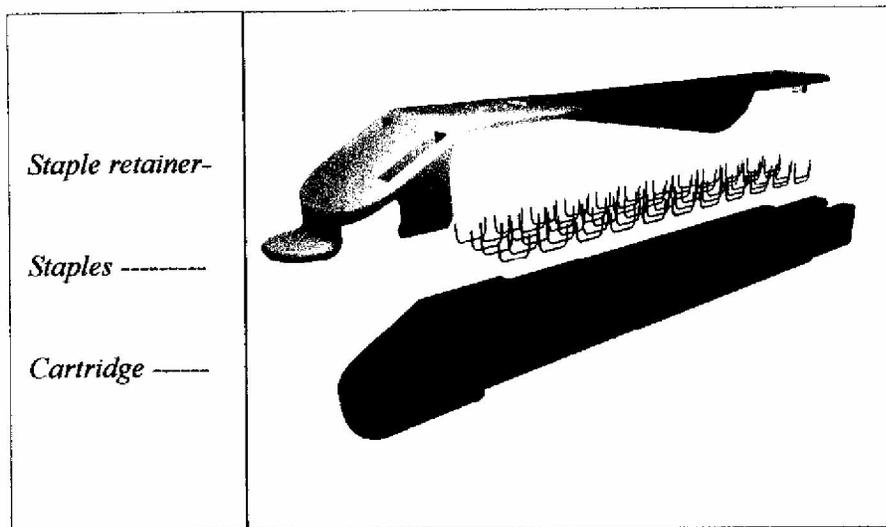
In general, these linear cutter and stapler instruments are intended for use in transection and resection of tissue during multiple open or minimally invasive surgical procedures. Linear cutter instruments are also intended for use in the creation of anastomoses in these procedures. Specific instrument indications are provided in specific instrument product insert labeling.

(b)(4)

(b)(4)

A schematic of the Gray Cartridge device assembly is shown in Figure 1: Gray Cartridge Device Assembly (next page). The device consists of the cartridge, the staples and the staple retainer (which is to be removed before use).

Figure 1: Gray Cartridge Device Assembly



Engineering drawings of the Gray Cartridge and the White Cartridge device assemblies are furnished at the end of this Section.

Purpose of this Premarket Notification

The purpose of this submission is to notify FDA of Ethicon Endo-Surgery, Inc.’s intent to market a Gray Cartridge Reload as an additional reload to the ENDOPATH Endocutter product line. This modification is to be called the ENDOPATH Endocutter Gray Cartridge.

The Gray Cartridge reload is (b)(4) the existing 45mm product line. Currently available reloads which are compatible with the 45mm product line are the white cartridge, blue cartridge and green cartridge. See Table 1: Cartridge Reload Information below.

Table 1: Cartridge Reload Information

Product Code	Color of Cartridge	Number of Rows	Nominal Closed Staple Height
6R45M (new)	Gray	6 row	0.85mm
TR45W	White	6 row	1.0mm
6R45B	Blue	6 row	1.5mm
TR45B	Blue	4 row	1.5mm
TR45G	Green	4 row	2.0mm

A (b)(4) the addition of the following contraindication statement: **“Do not use the instruments with gray reload on any tissue that requires excessive force to compress to 0.85mm or any tissue that compresses easily to below 0.85mm.”** This statement is consistent with the Contraindications for other size reloads (e.g., for the white reload, the statement reads: “Do not use the instruments with

white reload on any tissue that requires excessive force to compress to 1.0mm or on any tissue that compresses easily to below 1.0mm.”).

Indications for Use

The ENDOPATH ETS45 Endoscopic Linear Cutters, the ETS-Flex45 Endoscopic Articulating Linear Cutters, and the ETS Compact-Flex45 Articulating Linear Cutters are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

The ENDOPATH ETS-Flex-45 No-Knife Articulating Linear Staplers and the ETS Compact-Flex45 No-Knife Articulating Linear Staplers are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

Regulatory History of the Device

Ethicon Endo-Surgery, Inc. has commercially marketed the ENDOPATH® Endocutter product line for several years. Information on devices to which substantial equivalence is claimed is contained in the following submissions, the most recent being mentioned first.

Premarket Notification Submission Number K020779

The ENDOPATH and PROXIMATE Linear Cutters and Staplers were the subject of Premarket Notification Submission K020779, which received concurrence on June 5, 2002. (b)(4)

(b)(4)

(b)(4)

Premarket Notification Submission Number K002398

The ENDOPATH ETS45 Linear Cutters, Staplers and Reloads were the subject of Premarket Notification Submission K002398, which received concurrence on November 3, 2000. The purpose of that submission was to notify FDA of a change to the design of

(b)(4)

Premarket Notification Submission Number K980815

The ENDOPATH EZ45 Endoscopic Linear Cutters were the subject of Premarket Notification Submission K980815, which received concurrence on May 1, 1998. The purpose of that submission was to notify FDA that Ethicon Endo-Surgery, Inc. intended

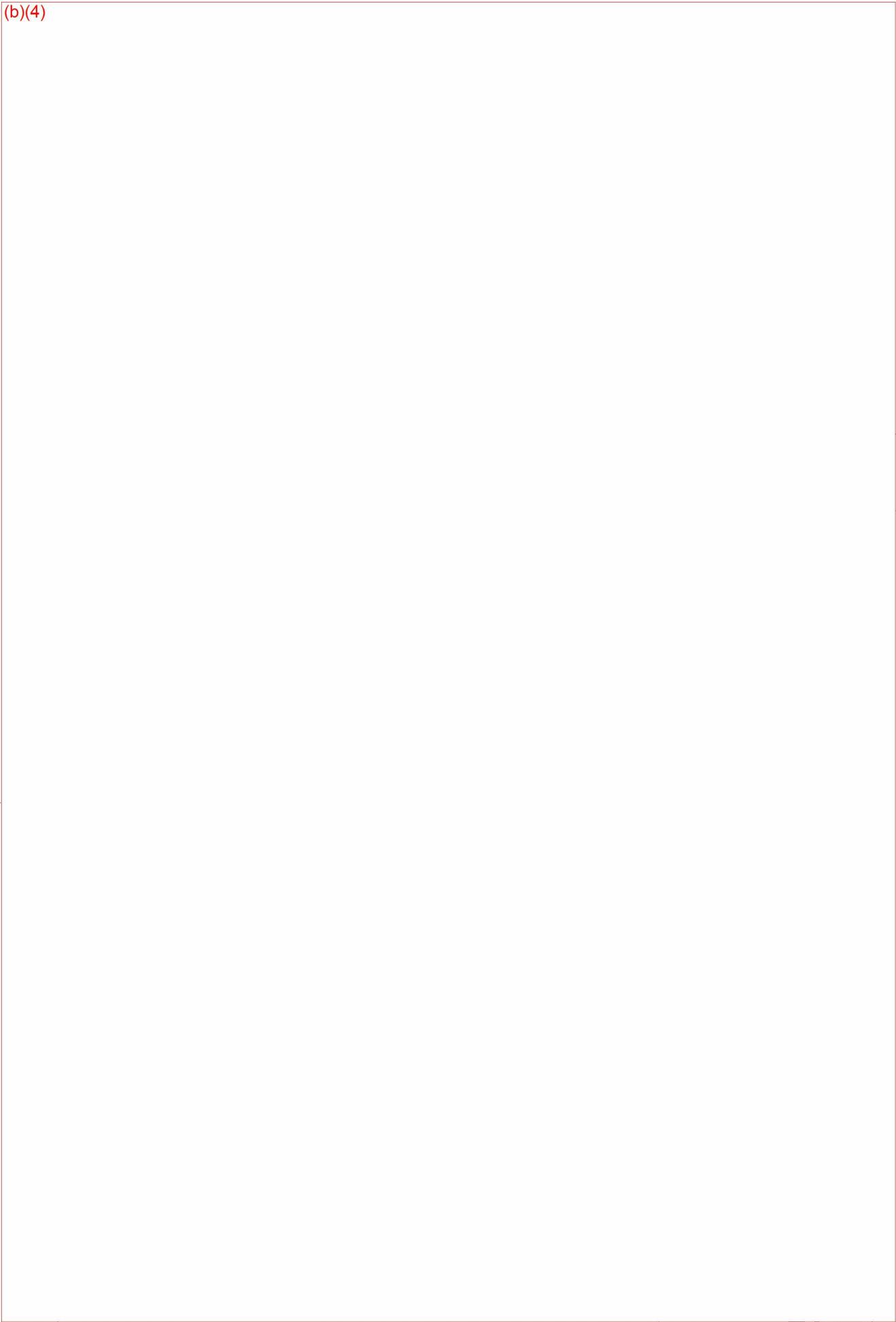
(b)(4)

Premarket Notification Submission Number K961390

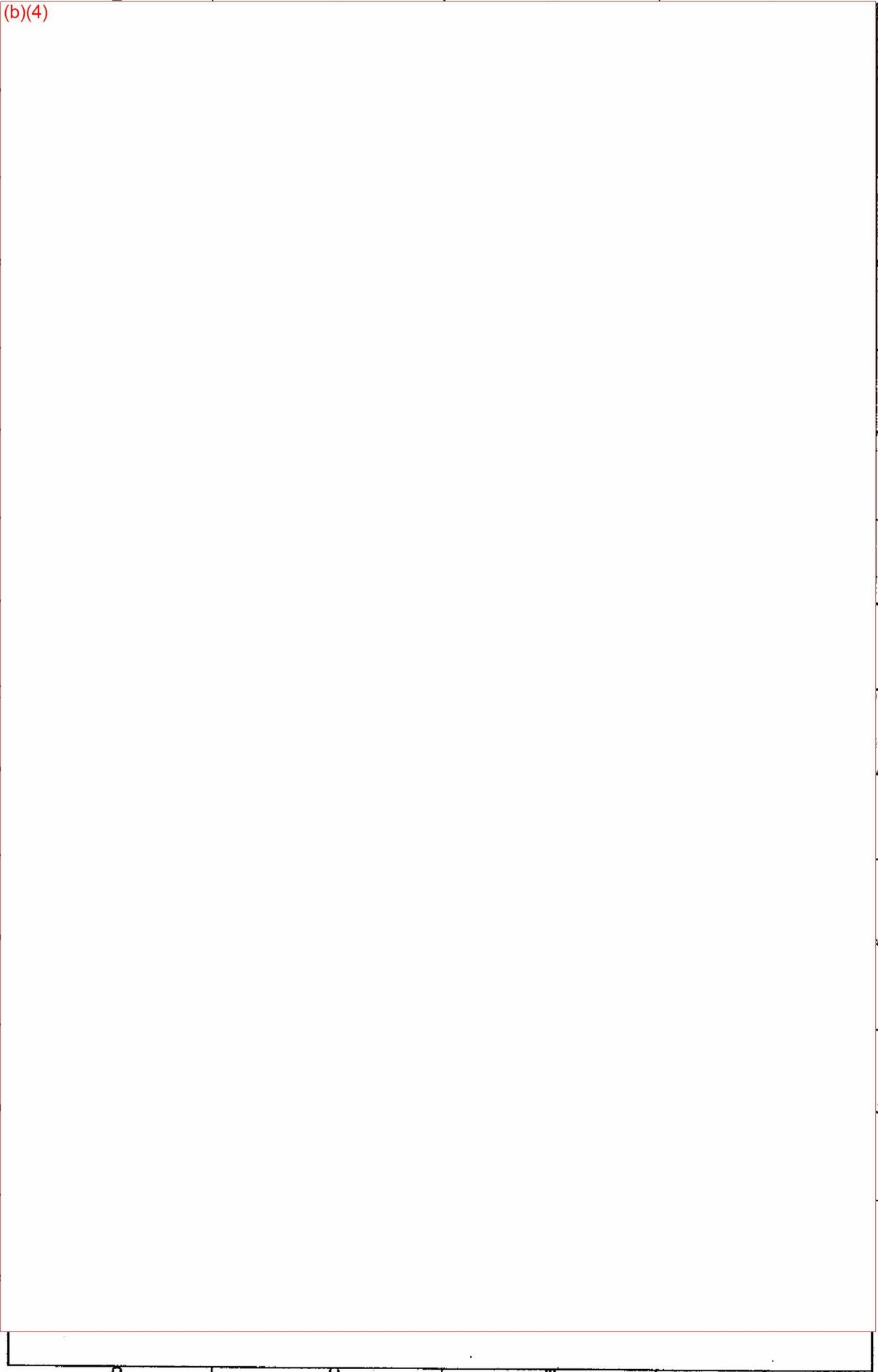
The ENDOPATH® ETS Endoscopic Linear Cutter and ETS-Flex Endoscopic Articulating Linear Cutter Devices were the subject of Premarket Notification Submission K961390, which received concurrence on June 25, 1996. The purpose of that submission was to notify FDA that Ethicon Endo-Surgery, Inc. intended to market a

(b)(4)

(b)(4)



(b)(4)



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Section F

Device Materials and Biocompatibility

The biocompatibility of materials used in the Gray Cartridge was evaluated based on EN ISO 10993-1: “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing” and on FDA General Program Memorandum #G95-1: Use of International Standard ISO-10993, “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing.”

Each material in the modified device was assessed for biocompatibility using FDA guidelines and the ISO 10993-1 standard, and each was found to be biocompatible. Documentation of the results of this testing is maintained at the Ethicon Endo-Surgery, Inc. facility.

(b)(4)

currently are colored green, the standard tissue reload cartridges are blue and the vascular/thin tissue reload cartridges are white, thereby making each size easily distinguishable from the other sizes. The mesentery/thin tissue reload cartridges, subject of this submission, are gray.

(b)(4)

(b)(4)

greater than 30 days of patient contact in accordance with the ISO 10993-1 standard and FDA Memorandum #G95-1. (b)(4)

(b)(4)

It is anticipated (b)(4)

(b)(4)

(b)(4)

Materials with limited patient contact (<24 hours) were evaluated per the requirements of ISO 10993-1 and successfully met the requirements for cytotoxicity, guinea pig sensitization (maximization design), intracutaneous toxicity (irritation), as well as the FDA Memorandum #G95-1 recommended systemic toxicity test.

All materials in the Gray Cartridge meet the biocompatibility requirements for the appropriate level of tissue contact.

Section G

Performance Testing and Animal Studies

Bench Testing

Bench testing to evaluate (b)(4) conducted with satisfactory results.

Criteria For Success:

- The (b)(4) Ethicon Endo-Surgery, Inc. (EES) White Cartridge.
- (b)(4)
(b)(4)

Methods:

(b)(4)

Devices Tested:

(b)(4)

(b)(4)

Results:

(b)(4)

Conclusion of Bench Testing:

The Gray Cartridge device (b)(4) and meets the design/product (b)(4) requirements.

Animal Studies

Acute animal studies were conducted to assess the performance of the Gray Cartridge as

(b)(4)



Methods:

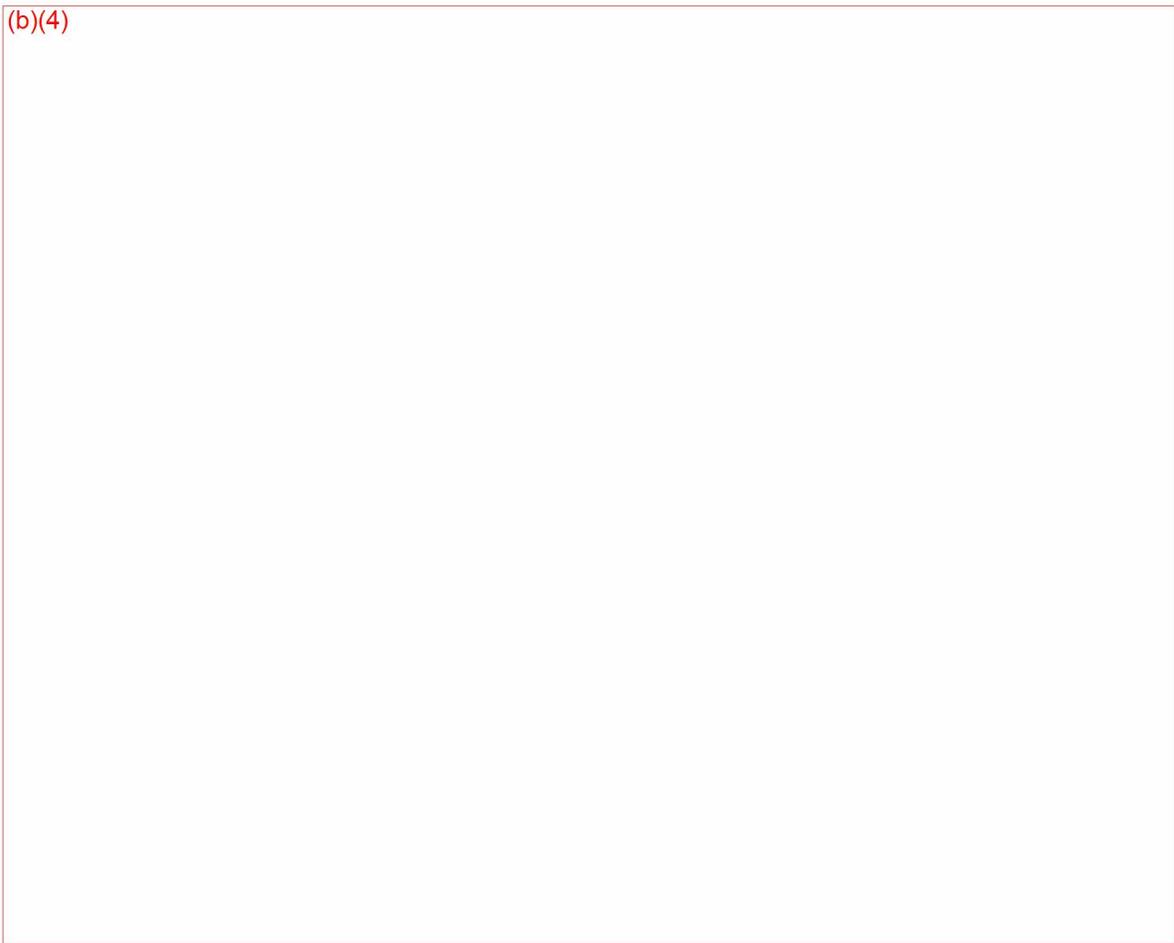
(b)(4)

Devices Tested:

(b)(4)

Results:

(b)(4)



(b)(4)



Study 2 - (b)(4)

Objective:

(b)(4)

Methods:

(b)(4)

Devices Tested:

(b)(4)

Results:

(b)(4)

(b)(4)

Conclusion of Study #2:

- (b)(4)

-

-

Summary of Overall Performance Data

Based upon bench testing and acute evaluations of hemostasis, the Gray Cartridge has been demonstrated to perform similarly to the predicate Ethicon Endo-Surgery Inc. White Cartridge reload device (b)(4)

Section H

Sterilization and Packaging

Sterilization

Sterilization of the device is identical to the marketed device. The device is sterilized by gamma irradiation. Radiation qualifications are performed according to the requirements in ISO 11137-1994 *Sterilization of Health Care Products – Requirements for Validation and Routine Control – Radiation Sterilization*. Validation requires a minimum of 25 kGy to achieve a 10^{-6} sterility assurance level (SAL).

The device is intended for single patient use and is not intended to be reused or resterilized.

Packaging

Each ENDOPATH Endocutter Gray Cartridge is packaged (b)(4)

(b)(4)

Section I

Labeling

(b)(4) made to the labeling are to clearly identify that this device is for use on mesentery/thin and vascular tissue, and to reflect a new Contraindication for tissue compression range associated with the new staple dimensions.

A labeling (b)(4) Section includes the addition of the following contraindication statement: **“Do not use the instruments with gray reload on any tissue that requires excessive force to compress to 0.85mm or any tissue that compresses easily to below 0.85mm.”** This statement is consistent with the Contraindications for other size reloads (e.g., for the white reload, the statement reads: “Do not use the instruments with white reload on any tissue that requires excessive force to compress to 1.0mm or on any tissue that compresses easily to below 1.0mm.”).

Section J

Statement of Substantial Equivalence

The “510(k) Substantial Equivalence Decision Making Process (Detailed) Decision Tree” (Blue Book Memorandum K86-3, 1986) was used in determining substantial equivalence of the ENDOPATH® Endocutter Gray Cartridge to the predicate device. The decision-making chart, with the path applicable to this submission highlighted, is provided in Appendix J-1.

New device is compared to marketed device

Marketed device: ENDOPATH & PROXIMATE Linear cutters and Staplers cleared under K020779 on 6/5/2002
 ENDOPATH ETS45 Endoscopic Linear Cutter cleared under K002398 on 11/3/2000
 ENDOPATH EZ45 Endoscopic Linear Cutter cleared under K980815 on 5/1/98
 ENDOPATH ETS Endoscopic Linear Cutter and ETS-Flex Endoscopic Articulating Linear Cutter Devices cleared under K961390 on 6/25/96.

New device: ENDOPATH Endocutter Gray Cartridge

Does new device have same indications statement?

Yes. The Indications for Use statement is identical.

The ENDOPATH ETS45 Endoscopic Linear Cutters, the ETS-Flex45 Endoscopic Articulating Linear Cutters, and the ETS Compact-Flex45 Articulating Linear Cutters are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

The ENDOPATH ETS-Flex-45 No-Knife Articulating Linear Staplers and the ETS Compact-Flex45 No-Knife Articulating Linear Staplers are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

Does the device have the same technological characteristics, (e.g., design, materials, etc.)?

No. This is for the addition of a smaller height (0.85mm) (b)(4) staple reload to an existing product line. Materials are identical to those of the currently marketed device (b)(4)

Could the new characteristics affect safety or effectiveness?

Yes. Material changes and minor design changes could affect safety or effectiveness.

Do the new characteristics raise new types of safety or effectiveness questions?

No, they do not raise new types of safety or effectiveness questions. The new reload is identical to the marketed device except for the size of the staples and the color of the cartridge.

Do accepted scientific methods exist for assessing effects of new characteristics?

Yes. Test methods exist for assessing functionality (b)(4)
(b)(4) Refer to Section G, Performance Testing and Animal Studies.
Biocompatibility can be evaluated based on the ISO 10993-1 standard and on FDA Guidelines. Refer to Section F, Device Materials and Biocompatibility.

Are performance data available to assess effects of new characteristics?

Yes. Testing was performed to ensure that the new characteristics perform equivalently and that the new materials were assessed for biocompatibility. Refer to Section G, Performance Testing and Animal Studies and Section F, Device Materials and Biocompatibility.

Performance data demonstrate equivalence?

Yes. The device continues to perform equivalently.

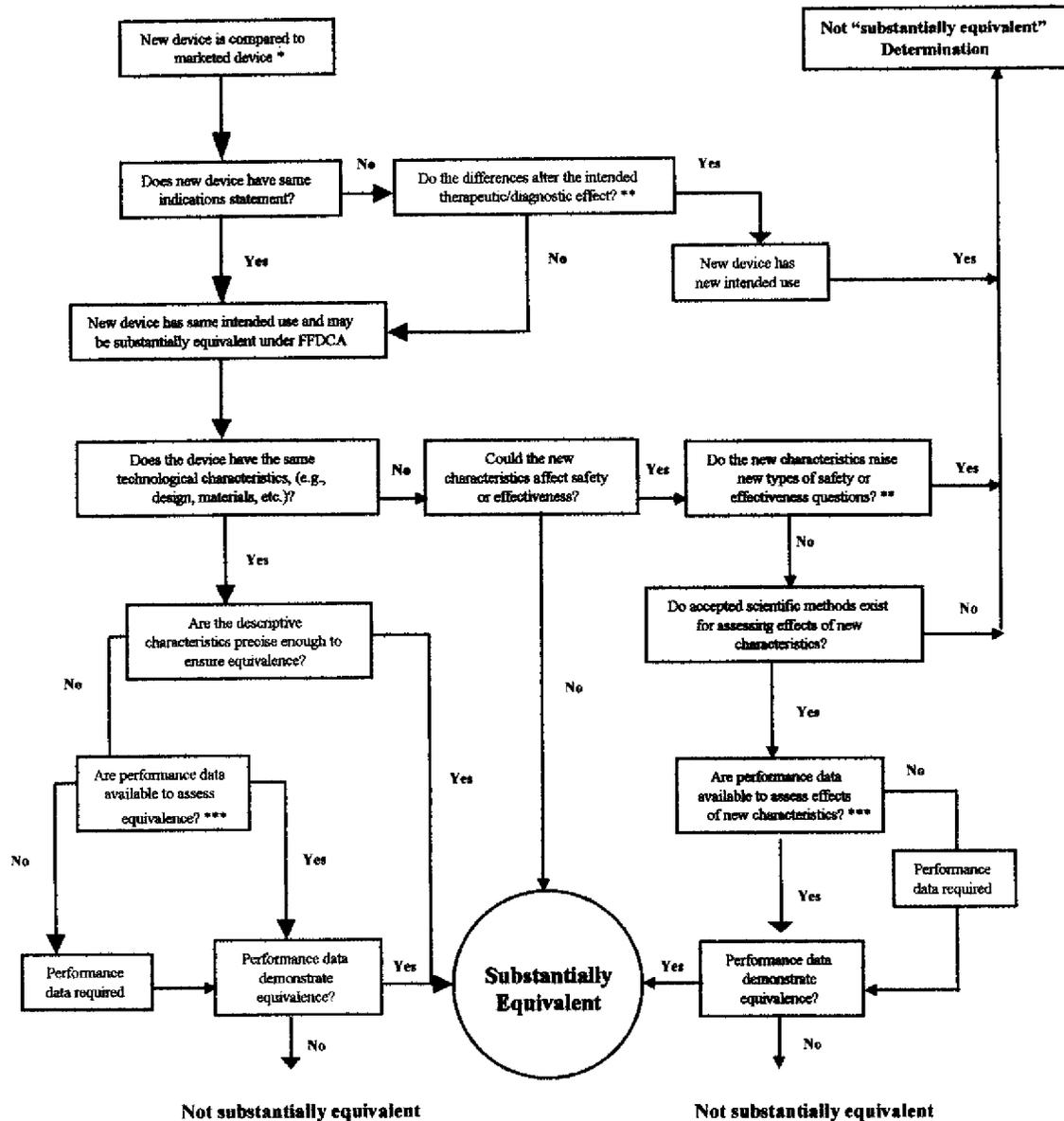
Substantially Equivalent Determination

Appendix J-1

Substantial Equivalence Decision Making Process Decision Tree

The Substantial Equivalence Decision Making Process Decision Tree for the proposed device is provided on the following page.

510(k) Substantial Equivalence Decision Making Process (Detailed) Decision Tree (CDRH 510(k) Manual 92-4158)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship

** 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.

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Section K

510(k) Summary of Safety and Effectiveness Information

The 510(k) Summary of Safety and Effectiveness Information for the proposed device is on the following pages. An extra copy has been included in a plastic sleeve for reviewer convenience.

510(k) Summary of Safety and Effectiveness Information

Company Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242

Contact Georgia C. Abernathy, MBA, RAC
Senior Regulatory Affairs Associate
Telephone: (513) 337-3179
Fax: (513) 337-1444
Email: gabernat@eesus.jnj.com

Date Prepared October 8, 2003

Device Name Trade Name: ENDOPATH® Endocutter Gray Cartridge
Classification Name: Endoscope and Accessories, Implantable Staples

Predicate Device ENDOPATH® Linear Cutters and Staplers

Device Description These instruments are all mechanical surgical stapling devices. The ENDOPATH Linear Cutter models are sterile single use instruments that deliver staples while simultaneously dividing tissue between rows. The ENDOPATH No-Knife Staplers are sterile single use instruments that deliver staples, but do not cut. These instruments may be used in either open or Endoscopic procedures, depending upon the design. Some instruments are Reloadable and, if so, they may be reloaded with various reloads (i.e., vascular/thin, standard, thick) depending on the thickness of tissue that is to be transected or resected.

Indications for Use

The ENDOPATH ETS45 Endoscopic Linear Cutters, the ETS-Flex45 Endoscopic Articulating Linear Cutters, and the ETS Compact-Flex45 Articulating Linear Cutters are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

The ENDOPATH ETS-Flex-45 No-Knife Articulating Linear Staplers and the ETS Compact-Flex45 No-Knife Articulating Linear Staplers are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

Technological Characteristics This is an addition of a gray cartridge reload to this product line. The Gray Cartridge is for use on thin tissue such as mesentery and vessels and has a nominal closed staple height of 0.85mm.

Performance Data Bench testing and pre-clinical laboratory evaluations were performed to demonstrate that the device will perform as intended.

Section L

Draft Product Labeling

Draft labels and Package Insert for the proposed device are included.

Draft Labeling

Package Component Copy

Sales Label – Multilingual

1 ENDOPATH® ETS45 Gray Reload

(b)(4)

CONTENTS: One instrument designed for single patient use.

Sterilized by irradiation. Sterility guaranteed unless package opened or damaged.
DO NOT RESTERILIZE.

SEE INSTRUCTIONS FOR USE.

R_x Only

Single Patient Use.

LOT

CE with #

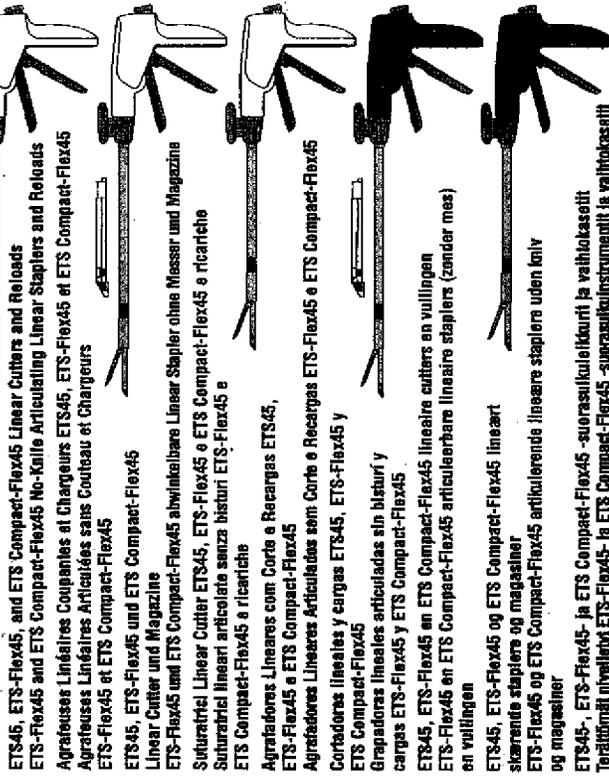
ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company
4545 Creek Road
Cincinnati, Ohio 45242-2839

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P4XXXX2PX

Assembled in Mexico

ENDOPATH®



ETS45, ETS-Flex45, and ETS Compact-Flex45 Linear Cutters and Reloads
 ETS-Flex45 and ETS Compact-Flex45 No-Knife Articulating Linear Staplers and Reloads

Agrafeuses Linéaires Coupantes et Chargeurs ETS45, ETS-Flex45 et ETS Compact-Flex45
 Agrafeuses Linéaires Articulées sans Couteau et Chargeurs ETS-Flex45 et ETS Compact-Flex45

ETS45, ETS-Flex45 und ETS Compact-Flex45
 Linear Cutter und Magazine

ETS-Flex45 und ETS Compact-Flex45 abwinkelbare Linear Stapler ohne Messer und Magazine
 Substrätriel Linear Cutter ETS45, ETS-Flex45 et ETS Compact-Flex45 e ricariche

Substrätriel lineari articulata senza bisturi ETS-Flex45 e
 ETS Compact-Flex45 e ricariche

Agrafadores Lineares com Corte e Recargas ETS45,
 ETS-Flex45 e ETS Compact-Flex45

Agrafadores Lineares Articulados sem Corte e Recargas ETS-Flex45 e ETS Compact-Flex45
 Cortadores lineales y cargos ETS45, ETS-Flex45 y ETS Compact-Flex45

Grapadoras lineales articuladas sin bisturi y
 cargos ETS-Flex45 y ETS Compact-Flex45

ETS45, ETS-Flex45 en ETS Compact-Flex45 lineaire cutters en vullingen
 ETS-Flex45 en ETS Compact-Flex45 articulerende lineaire staplers (zonder mes)

en vullingen
 ETS45, ETS-Flex45 og ETS Compact-Flex45 lineært skærende staplers og magasiner

ETS-Flex45 og ETS Compact-Flex45 artikulerende lineære staplere uden kniv og magasiner

ETS45-, ETS-Flex45- ja ETS Compact-Flex45 -suorasulkuleikkurit ja vaihtokassettit
 Toistilittämälä mivellötyt ETS-Flex45- ja ETS Compact-Flex45 -suorasulkuvälineillä ja vaihtokassettit

Агрегаторы линейных, координируемых, ETS45, ETS-Flex45 и ETS Compact-Flex45
 Агрегаторы линейных артикулируемых линейных степлеров (без ножа) ETS-Flex45 и ETS Compact-Flex45

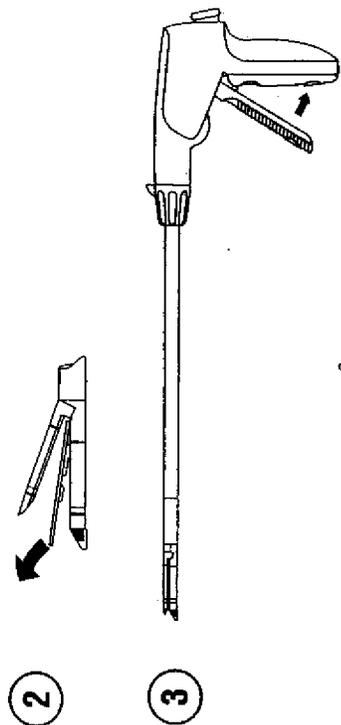
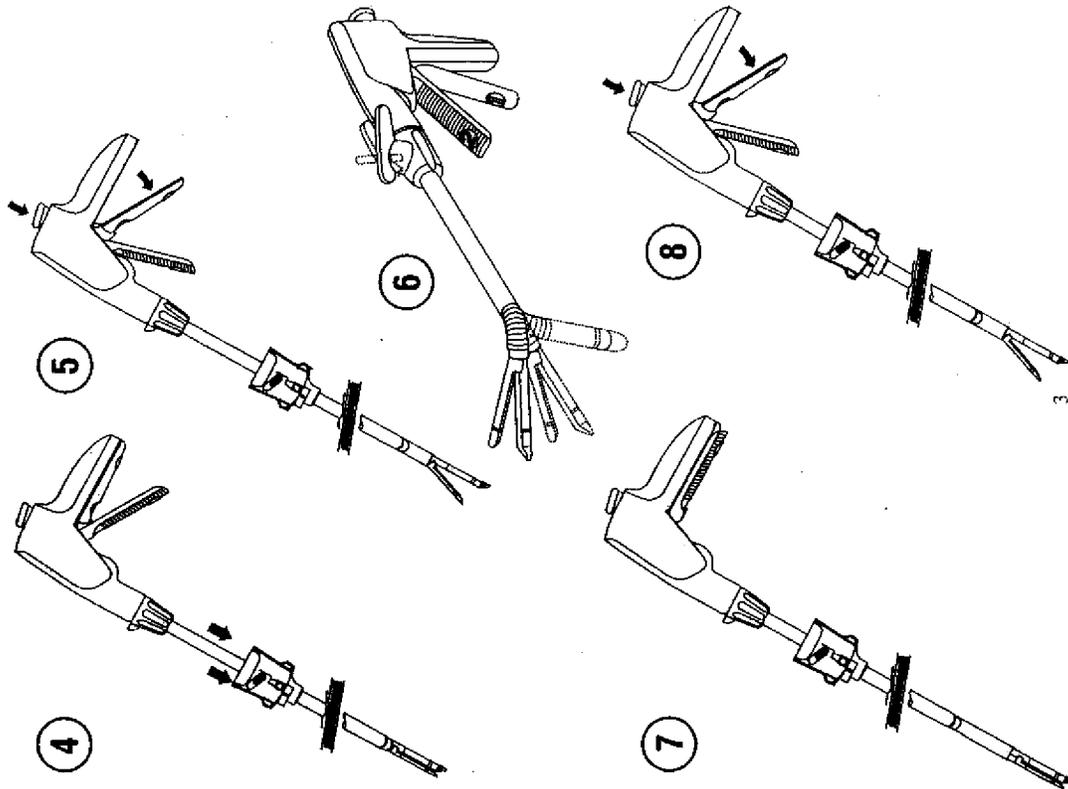
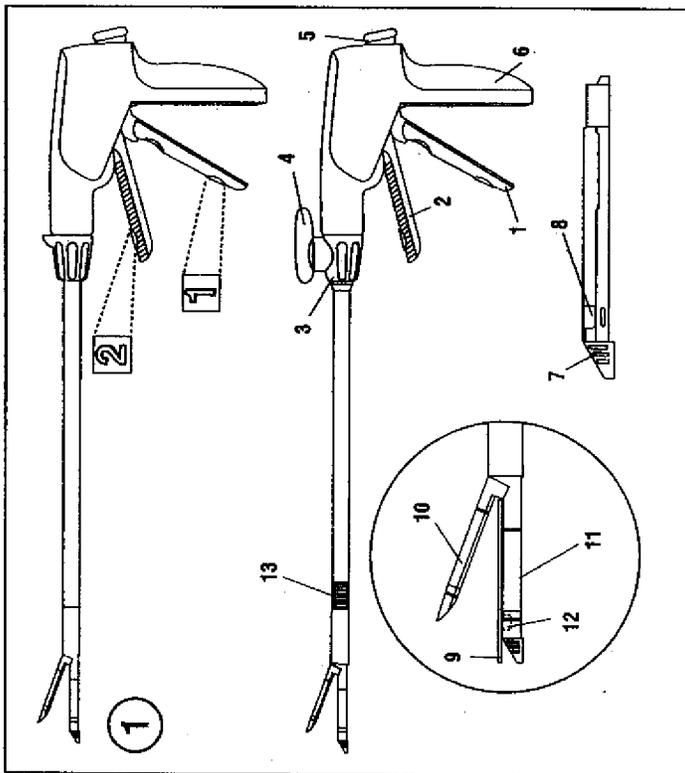
ETS45, ETS-Flex45 och ETS Compact-Flex45 linjära skärande stapler med magasin
 ETS-Flex45 och ETS Compact-Flex45 artikulerande linjära stapler utan kniv med magasin

エンドパス®
 ETS45, ETS Flex45, ETS Compact-Flex45 リニヤークッターおよびカートリッジ
 ETS Flex45, ETS Compact-Flex45 (ナイフ無) アーティキュレート型リニヤーステップラー
 およびカートリッジ



ETHICON ENDO-SURGERY, INC.
 a Johnson & Johnson company

Instructions, Instructions, Gebrauchsanweisung, Istruzioni, Instrucciones, Instrucciones,
 Gebrauchsanweisung, 取扱説明書, 取扱説明書, 取扱説明書, 取扱説明書, 取扱説明書



Please read all information carefully.

Failure to properly follow the instructions may lead to serious surgical consequences, such as leakage or disruption.

Important: This package insert is designed to provide instructions for use of the ENDOPATH ETS45 Endoscopic Linear Cutters, the ETS-Flex45 Endoscopic Articulating Linear Cutters, the ETS Compact-Flex45 Articulating Linear Cutters, the ETS-Flex45 No-Knife Articulating Linear Staplers, ETS Compact-Flex45 No-Knife Articulating Linear Staplers and reloads. It is not a reference to surgical techniques.

Indications

The ENDOPATH ETS45 Endoscopic Linear Cutters, the ETS-Flex45 Endoscopic Articulating Linear Cutters, and the ETS Compact-Flex45 Articulating Linear Cutters are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

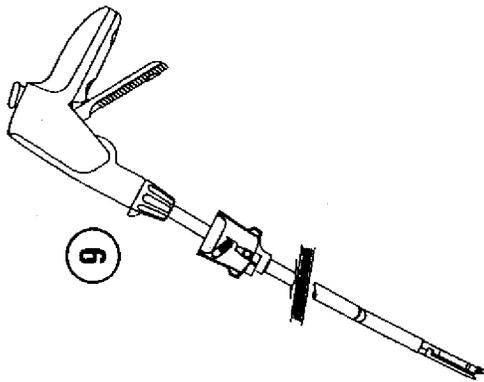
The ENDOPATH ETS-Flex45 No-Knife Articulating Linear Staplers and the ETS Compact-Flex45 No-Knife Articulating Linear Staplers are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

Contraindications

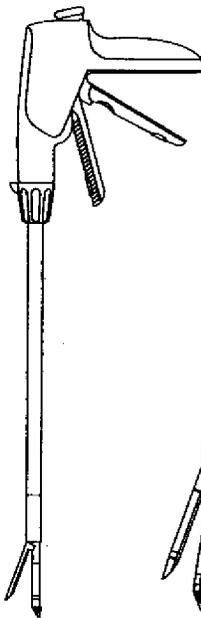
- Do not use the instruments with green reload on any tissue that requires excessive force to compress to 2.0 mm or on any tissue that compresses easily to below 2.0 mm.
- Do not use the instruments with blue reload on any tissue that requires excessive force to compress to 1.5 mm or on any tissue that compresses easily to below 1.5 mm.
- Do not use the instruments with white reload on any tissue that requires excessive force to compress to 1.0 mm or on any tissue that compresses easily to below 1.0 mm.
- Do not use the instruments with gray reload on any tissue that requires excessive force to compress to 0.85 mm or on any tissue that compresses easily to below 0.85 mm.
- Do not use the instruments on ischemic or necrotic tissue.
- Do not use the instruments on the aorta.
- Do not use any linear cutter on major vessels without making provision for proximal and distal control.
- Do not use the instruments on solid organs, such as the liver or spleen, where attempted compression would be destructive.
- These instruments are not intended for use when surgical stapling is contraindicated.

Device Descriptions

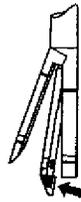
The ENDOPATH ETS45, ETS-Flex45, and ETS Compact-Flex45 Linear Cutters are sterile, single patient use instruments that deliver staples while simultaneously dividing tissue between rows. ETS45 instruments with blue (standard) reloads deliver two double- or triple- staggered rows of staples; ETS45 instruments with green (thick) reloads deliver two double-staggered rows of staples only; ETS45 instruments with white (vascular) reloads deliver two triple-staggered rows of staples; and, ETS45 instruments with gray (mesenteric) reloads deliver two triple-staggered rows of staples. The instruments' safety lock-out feature is designed to prevent a used reload from being refired. The instruments have a staple line that is approximately 45 mm long and a cut line that is approximately 41 mm long. A staple retaining cap on the



9



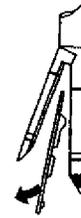
10



11



12



English

reload protects the staple leg points during shipping and transportation. An articulation lever on the ETS-Flex45 and ETS Compact-Flex45 Articulating Linear Cutters enables bilateral movement of the instrument jaws.

The ENDOPATH ETS-Flex45 and ETS Compact-Flex45 No-Knife Linear Staplers are sterile, single patient use instruments. ETS45 instruments with blue (standard) reloads deliver two double- or triple-staggered rows of staples; ETS45 instruments with green (thick) reloads deliver two double-staggered rows of staples only; ETS45 instruments with white (vascular) reloads deliver two triple-staggered rows of staples; and, ETS45 instruments with gray (mesenteric) reloads deliver two triple-staggered rows of staples. The instruments' safety lock-out feature is designed to prevent a used reload from being re-fired. The instruments have a staple line that is approximately 45 mm long. A staple retaining cap on the reload protects the staple leg points during shipping and transportation. An articulation lever on the instruments enables bilateral movement of the instrument jaws.

The instruments are loaded with a mesenteric, gray reload; a vascular, white reload; a standard, blue reload; or a thick tissue, green reload. ETS45 reloads are interchangeable across all ETS45 family instrument codes. For example, a TSW45 instrument, which is provided with a TR45W reload, may be reloaded with either the TR45B, the TR45G, the TR45W, the 6R45B, or the 6R45M.

Do not reload the instruments more than seven times for a maximum of eight firings per instrument. The use of the instrument with staple line buttressing material may reduce the number of firings. Use only the indicated reloads in the ETS45 instrument. Do not use ETS45 family reloads in an instrument other than an ETS45 family instrument.

ETS45 Product Family

Instrument Code	Description	Shaft Length
TSW45	ETS45 Endoscopic Linear Cutter, Vascular	340 mm
TSB45	ETS45 Endoscopic Linear Cutter, Standard	340 mm
TSG45	ETS45 Endoscopic Linear Cutter, Thick Tissue	340 mm
6SB45	ETS45 Endoscopic Linear Cutter, Standard (6 Rows)	340 mm
ATW45	ETS-Flex45 Endoscopic Articulating Linear Cutter, Vascular	340 mm
ATB45	ETS-Flex45 Endoscopic Articulating Linear Cutter, Standard	340 mm
ATG45	ETS-Flex45 Endoscopic Articulating Linear Cutter, Thick Tissue	340 mm
6TB45	ETS-Flex45 Endoscopic Articulating Linear Cutter, Standard (6 Rows)	340 mm
SCW45	ETS Compact-Flex45 Endoscopic Articulating Linear Cutter, Vascular	240 mm
SCB45	ETS Compact-Flex45 Endoscopic Articulating Linear Cutter, Standard	240 mm
SCG45	ETS Compact-Flex45 Endoscopic Articulating Linear Cutter, Thick Tissue	240 mm

6CB45	ETS45 Compact-Flex45 Endoscopic Articulating Linear Cutter, Standard (6 Rows)	240 mm
MAW45	ETS-Flex45 No-Knife Articulating Linear Stapler, Vascular	340 mm
MAB45	ETS-Flex45 No-Knife Articulating Linear Stapler, Standard	340 mm
MAG45	ETS-Flex45 No-Knife Articulating Linear Stapler, Thick Tissue	340 mm
NSW45	ETS Compact-Flex45 No-Knife Articulating Linear Stapler, Vascular	240 mm
NSB45	ETS Compact-Flex45 No-Knife Articulating Linear Stapler, Standard	240 mm
NSG45	ETS Compact-Flex45 No-Knife Articulating Linear Stapler, Thick Tissue	240 mm
LONG45A	ETS-Flex45 Endoscopic Articulating Long Linear Cutter, No Reload	440 mm

Specifications for ETS45 family reloads follow:

Supported Instrument Codes: TSW45, TSB45, TSG45, ATW45, ATB45, ATG45, SCW45, SCB45, SCG45, MAW45, MAB45, MAG45, NSW45, NSB45, NSG45, LONG45A, 6SB45, 6TB45, 6CB45, 6GB45.

Reload Code	Description	Staple Leg Length	Closed Staple Height	Number of Staples	Reload Color	Staple Rows
TR45G	Thick	4.1 mm	2.0 mm	44	Green	4
TR45B	Standard	3.5 mm	1.5 mm	44	Blue	4
6R45B	Standard	3.5 mm	1.5 mm	66	Blue	6
TR45W	Vascular/Thin	2.5 mm	1.0 mm	66	White	6
6R45M	Mesenteric/Thin	2.0 mm	0.85 mm	66	Gray	6

Illustration and Nomenclature (Illustration 1)

- Closing Trigger (1)
- Firing Trigger (2)
- Rotating Knob
- Articulation Lever
- Anvil Release Button
- Handle
- Reload Gripping Surface
- Reload Alignment Tab
- Staple Retaining Cap
- Anvil Jaw
- Cartridge Jaw
- Reload Alignment Notch
- Articulation Joint

Instructions for Use

Verify compatibility of all instruments and accessories prior to using the instrument (refer to Warnings and Precautions).

Note: The following instruments cut and staple: TSW45, TSB45, TSG45, ATW45, ATB45, ATG45, SCW45, SCB45, SGG45, LONG45A, GSB45, 6TB45, 6CB45. The following instruments perform stapling only: NAB45, NAG45, NAW45, NSW45, NSB45, NSG45.

- 1 Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
- 2 Remove the staple retaining cap from the reload. Discard the staple retaining cap. (Illustration 2) Note: The staple retaining cap ensures proper staple orientation and protects the staple leg points during shipping and transportation.
- 3 Note: The LONG45A instrument is not preloaded. Remove the protective cover from the tip of the instrument before loading the instrument (see **Reloading the Instrument**). Close the jaws of the instrument by squeezing the closing trigger (light gray and labeled with a Number "1") until it locks in place. An audible click indicates that the closing trigger is locked. (Illustration 3)
- 4 **Caution:** Do not squeeze the firing trigger (dark gray and labeled with a Number "2") at this time. Introduce the instrument into the body cavity through the appropriate trocar or incision. (Illustration 4)

Caution: The instrument jaws must be closed to be introduced into the cavity through a trocar of the appropriate size.

- 5 Once in the cavity, press the anvil release button to reopen the instrument jaws and return the closing trigger (1) to its original position. (Illustration 5)
- 6 To articulate the instrument (articulating instruments only), turn the articulation lever until it comes to a stop in either direction. (Illustration 6)
- 7 **Caution:** Tissue damage or trauma may result if the instrument is articulated after closing on tissue. **Caution:** Attempting to force the articulation lever beyond its stop in either direction will result in instrument damage. After positioning the instrument jaws around the tissue to be stapled, close the jaws by squeezing the closing trigger (1) toward the handle until it locks. An audible click indicates that the closing trigger is locked. The tissue should be positioned between the black line at the distal end of the jaws and the black line at the proximal end indicating the ends of the staple line. The inner black line references the cut line of the device. Additionally, ensure that tissue has not milked behind the proximal black line. Tissue milked into the instrument beyond the black line may be transected without staples. Note: When firing across thick tissue, holding the tissue for 15 seconds after closing and prior to firing may result in better staple formation. **Caution:** If the closing trigger (1) is difficult to lock, reposition the instrument and take a smaller amount of tissue. (See **Contraindications** for appropriate reload selection.) **Caution:** Ensure that the tissue lies flat and is positioned properly between the jaws. Any "bunching" of tissue along the reload may result in an incomplete staple line. Note: The use of staple line buttressing materials with the instrument may require an increased force to close.

- 8 Fire the instrument by squeezing the firing trigger (2) completely until it rests on the closing trigger (1). (Illustration 7) Note: Once the firing cycle has been initiated, it must be completed. If re-initiation of firing is resumed, the instrument will lockout. If resonance is felt, stop and replace the cartridge. Firing through the lockout mechanism will break the instrument. **Caution:** The firing stroke must be completed. Do not partially fire the instrument. Note: The use of staple line buttressing materials with the instrument may require an increased force to fire and may reduce the number of firings. Note: Crossing of staple lines may shorten the life of the instrument.

- 9 Relax grip. Press the anvil release button to separate the instrument jaws and allow the closing and firing triggers to return to their original positions (Illustration 8). Before removing the instrument, make sure that tissue is removed from the jaws. **Caution:** After firing, examine the staple lines for pneumostasis/hemostasis and proper staple closure. If pneumostasis/hemostasis is not present, appropriate techniques should be used to achieve pneumostasis/hemostasis.

Caution: If the jaws do not automatically open after the anvil release button is pressed, pull the firing trigger (Number 2) upward (away from handle) until both firing and closing triggers return to their original positions. If the firing mechanism becomes inoperative, do not re-fire the instrument. (Remove and discard the instrument.) To remove the instrument from the cavity, squeeze the closing trigger (1) until it locks, closing the jaws. (Illustration 9) When removing the articulating instruments, the articulation lever must be straight, indicating that the jaws of the instrument are also straight. **Caution:** Failure to have the instrument jaws in the straight position will result in difficult withdrawal of the instrument and may result in breakage. Failure to straighten the instrument prior to reloading may prevent proper function of the fired cartridge lockout mechanism. Completely withdraw the instrument in the closed position.

Reloading the Instrument

- 1 Using sterile technique, remove the reload from the package. To avoid damage, do not flip the reload into the sterile field.
- 2 Prior to reloading, ensure the instrument is in the open position. (Illustration 10)
- 3 Push upward (toward the anvil) to unsnap the reload from the cartridge jaw. Discard the used reload. (Illustration 11) **Warning:** Prior to reloading the instrument, rinse the anvil and cartridge jaw in sterile solution and then wipe the anvil and cartridge jaw to clean any formed but unused staples from the instrument. Do not use the instrument until it has been visually inspected to confirm there are no staples on the anvil and cartridge jaw. Examine the new reload for the presence of a staple retaining cap. If the retaining cap is not in place, discard the reload. Note: Selection of the appropriate staple cartridge should be based upon the combined thicknesses of both the tissue and the staple line buttressing materials. Insert the new reload by sliding it against the bottom of the cartridge jaw until it stops in the reload alignment slot. Snap the reload securely in place. Remove the staple retaining cap and discard. The instrument is now reloaded and ready for use. (Illustration 12) **Caution:** After removing the staple retaining cap, observe the surface of the new reload. The reload must be replaced with another reload if any colored drivers are visible. (If colored drivers are visible, the reload may not contain staples.)

Warnings and Precautions

- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- Minimally invasive instruments may vary in diameter from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- A thorough understanding of the principles and techniques involved in laser, electro-surgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or

How Supplied

The ENDOPATH ETS45, ETS-Flex45, and ETS Compact-Flex45 Linear Cutters are supplied sterile for single patient use. Discard after use.

The ENDOPATH ETS-Flex45 and ETS Compact-Flex45 No-Knife Articulating Linear Staplers are supplied sterile for single patient use. Discard after use.

The reloads for use with the ENDOPATH ETS45, ETS-Flex45, and ETS Compact-Flex45 Linear Cutters are supplied sterile for single patient use. Discard after use.

The reloads for use with the ENDOPATH ETS-Flex45 and ETS Compact-Flex45 No-Knife Articulating Linear Staplers are supplied sterile for single patient use. Discard after use.

grounding is not compromised. Do not immerse electro-surgical instruments in liquid unless the instruments are designed and labeled to be immersed.

When dividing major vascular structures, be sure to adhere to the basic surgical principle of proximal and distal control.

Before using, remove the staple retaining cap and observe the surface of the reload. The reload must be replaced with another reload if any colored drivers are visible.

Ensure that the tissue lies flat and is positioned properly between the jaws. Any "bunching" of tissue along the reload may result in an incomplete staple line.

Prior to articulating and positioning the instrument jaws on tissue, make sure the jaws are in the open position.

The firing stroke must be completed. Do not partially fire the instrument.

Before removing the instrument, be sure tissue is cleared from the jaws and then close the jaws. Prior to removing the articulating instruments from the cavity, ensure the instrument is not articulated.

After removing the instrument, examine the staple line for pneumostasis/hemostasis and proper staple closure. If pneumostasis/hemostasis is not present, appropriate techniques should be used to achieve pneumostasis/hemostasis.

The instrument may be reloaded during a single procedure. Do not reload the instrument more than seven times for a total of eight firings per instrument.

The firing trigger (2) and closing trigger (1) must be in the open position during reloading.

Prior to reloading the instrument, rinse the anvil and cartridge jaw in sterile solution and then wipe the anvil and cartridge jaw to clean any formed but unused staples from the instrument. Do not use the instrument until it has been visually inspected to confirm there are no staples on the anvil and cartridge jaw.

If the jaws do not automatically open after the anvil release button is pressed, pull the firing trigger (Number 2) upward (away from handle) until both firing and closing triggers return to their original positions. If the firing mechanism becomes inoperative, do not refire the instrument. (Remove and discard the instrument.)

If the clamping mechanism becomes inoperative and the jaws do not clamp on tissue, do not fire the instrument. (Remove and discard the instrument and reload.)

Crossing of staple lines may shorten the life of the instrument.

When using a tissue or staple line buttressing material, the instructions of the manufacturer of the buttress material should be followed. The use of staple line buttressing materials with the instrument may require an increased force to fire and may reduce the number of firings.

Selection of the appropriate staple cartridge should be based upon the combined thicknesses of both the tissue and the staple line buttressing materials.

For removal of the articulating instruments, the articulation lever must be straight, indicating that the jaws of the instrument are also straight. Failure to have the instrument jaws in the straight position will result in difficult withdrawal of the instrument and may result in breakage. Failure to straighten the instrument prior to reloading may prevent proper function of the fired cartridge lockout mechanism.

Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.

Dispose of all opened instruments and reloads whether used or unused.

This device is packaged sterile in a protective pouch and is for single use only. Do not reuse, reprocess or sterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Also, reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

Section M

Marketed Device Labeling

Labeling for the ENDOPATH® Endocutter Gray Cartridge is provided.

Draft Labeling

Package Component Copy

Sales Label – Multilingual

1 ENDOPATH® ETS45 White Reload

(b)(4)

CONTENTS: One instrument designed for single patient use.

Sterilized by irradiation. Sterility guaranteed unless package opened or damaged.
DO NOT RESTERILIZE.

SEE INSTRUCTIONS FOR USE.

R_x Only

Single Patient Use.

LOT

CE with #

ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company
4545 Creek Road
Cincinnati, Ohio 45242-2839

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P4XXXX2PX

Assembled in Mexico

ENDOPATH®

ETS45, ETS-Flex45, and ETS Compact-Flex45 Linear Cutters and Reloads
 ETS-Flex45 and ETS Compact-Flex45 No-Knife Articulating Linear Staplers and Reloads
 Agrafadores Lineales Coupantes et Chargeurs ETS45, ETS-Flex45 et ETS Compact-Flex45
 Agrafadores Lineales Articulados sans Couteau et Chargeurs
 ETS-Flex45 et ETS Compact-Flex45

ETS45, ETS-Flex45 and ETS Compact-Flex45
 Linear Cutter and Magazine
 ETS-Flex45 and ETS Compact-Flex45 abwinkelbare Linear Stapler ohne Messer und Magazine
 Suturabriel Linear Culler ETS45, ETS-Flex45 e ETS Compact-Flex45 e ricariche
 Suturabriel lineari articolate senza bisturi ETS-Flex45 e
 ETS Compact-Flex45 e ricariche

Agrafadores Lineares com Corte e Recargas ETS45,
 ETS-Flex45 e ETS Compact-Flex45
 Agrafadores Lineares Articulados sem Corte e Recargas ETS-Flex45 e ETS Compact-Flex45

Cortadoras lineales y cargas ETS45, ETS-Flex45 y
 ETS Compact-Flex45
 Grapadoras lineales articuladas sin bisturi y
 cargas ETS-Flex45 y ETS Compact-Flex45

ETS45, ETS-Flex45 en ETS Compact-Flex45 lineaire cutters en vullingen
 ETS-Flex45 en ETS Compact-Flex45 articuleerbare lineaire staplers (zonder mes)
 en vullingen

ETS45, ETS-Flex45 og ETS Compact-Flex45 lineært
 skærende staplere og magasiner
 ETS-Flex45 og ETS Compact-Flex45 artikulerende lineære staplere uden kniv
 og magasiner

ETS45-, ETS-Flex45- ja ETS Compact-Flex45 -suorasulkuleikkurit ja vaihtokasetit
 Terätmittä nivelletyt ETS-Flex45- ja ETS Compact-Flex45 -suorasulkulinstrumentit ja vaihtokasetit

Ευθύγραμμοι κοπτοράβτες και Ανωαλλοκαταές κασέτες ETS45, ETS-Flex45 και ETS Compact-Flex45
 Αρθρώσιμα ευθύγραμμα συρραπτικά χωρίς λάμα και Ανωαλλοκαταές κασέτες ETS-Flex45 και
 ETS Compact-Flex45

ETS45, ETS-Flex45 och ETS Compact-Flex45 linjära skärande stapler med magasin
 ETS-Flex45 och ETS Compact-Flex45 artikulerande linjära stapler utan kniv med magasin

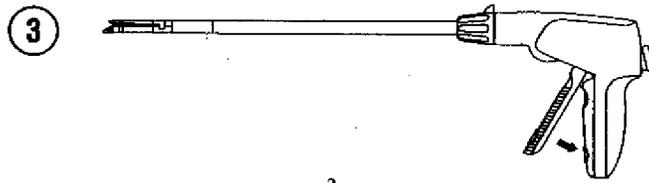
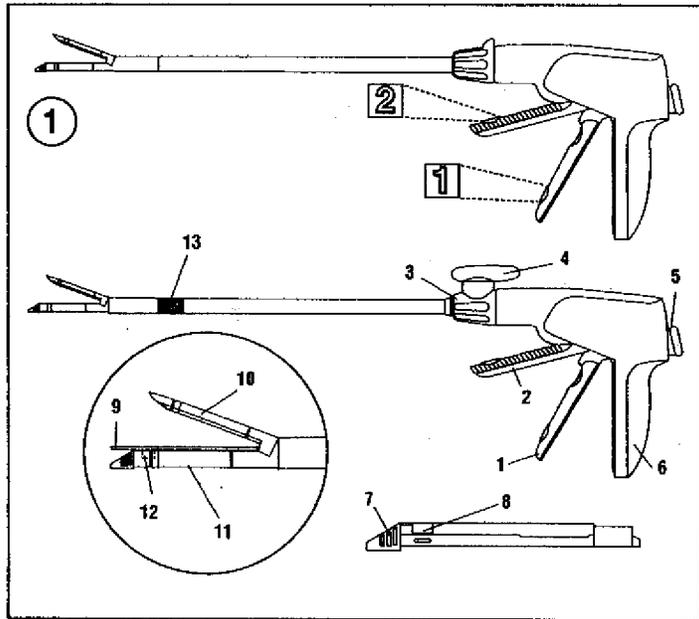


エンドパス*

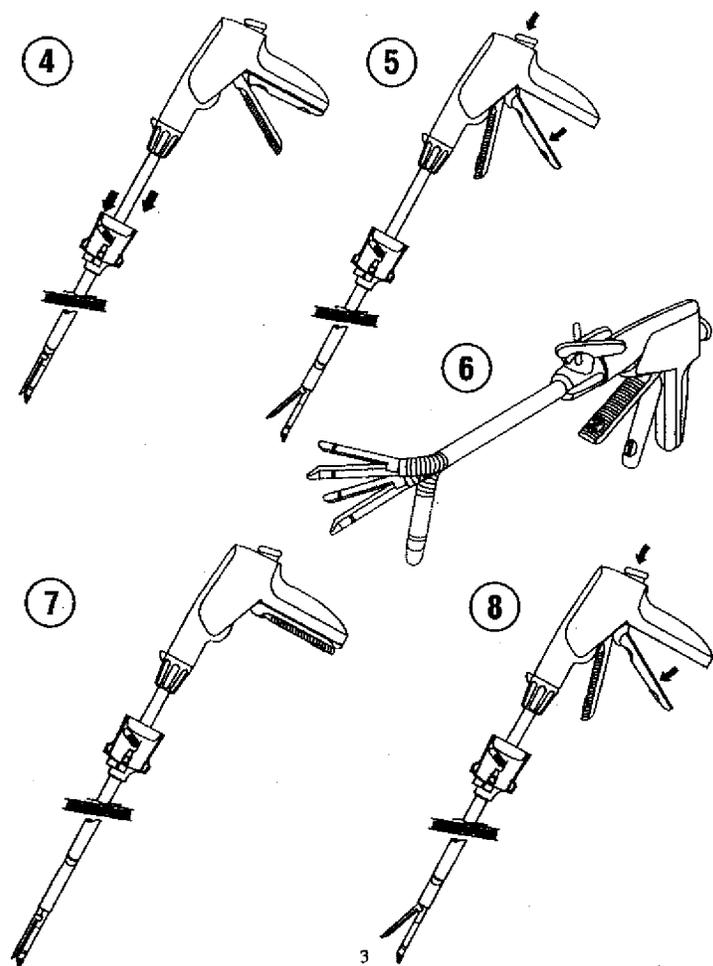
ETS45, ETS Flex45, ETS Compact-Flex45 リニヤーカッターおよびカートリッジ
 ETS Flex45, ETS Compact-Flex45 (ナイフ無) アーティキュレート型リニヤーステイプラーおよびカートリッジ

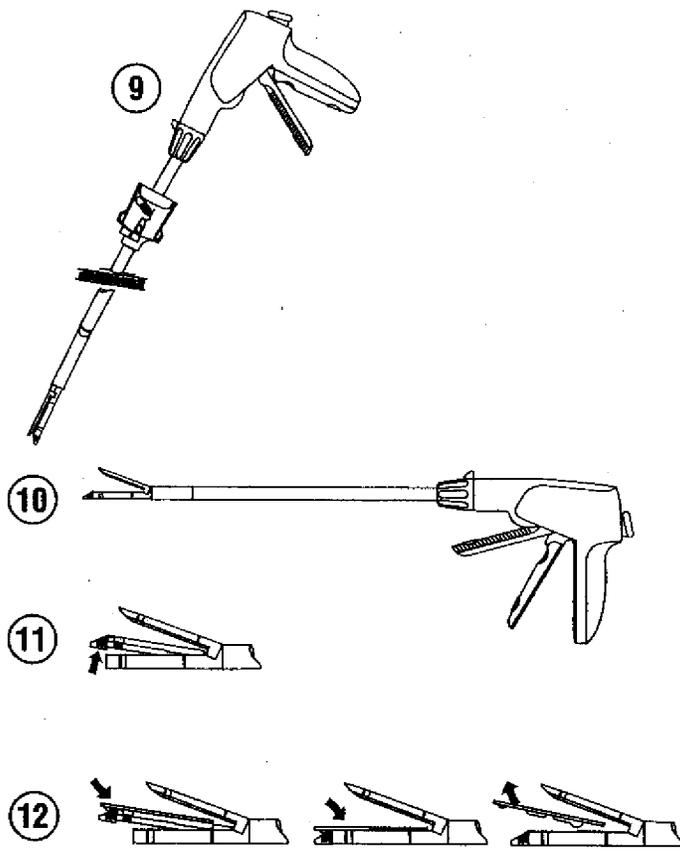


Instructions, Instructions, Gebrauchsanweisung, Istruzioni, Instrucciones, Instrucciones
 Gebrauchsanweisung, Bruksvejledning, Qija, o Bruksanvisning



2





Please read all information carefully.

Failure to properly follow the instructions may lead to serious surgical consequences, such as leakage or disruption.

Important: This package insert is designed to provide instructions for use of the ENDOPATH ETS45 Endoscopic Linear Cutters, the ETS-Flex45 Endoscopic Articulating Linear Cutters, the ETS Compact-Flex45 Articulating Linear Cutters, the ETS-Flex45 No-Knife Articulating Linear Staplers, ETS Compact-Flex45 No-Knife Articulating Linear Staplers and reloads. It is not a reference to surgical techniques.

Indications

The ENDOPATH ETS45 Endoscopic Linear Cutters, the ETS-Flex45 Endoscopic Articulating Linear Cutters, and the ETS Compact-Flex45 Articulating Linear Cutters are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

The ENDOPATH ETS-Flex45 No-Knife Articulating Linear Staplers and the ETS Compact-Flex45 No-Knife Articulating Linear Staplers are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

Contraindications

- Do not use the instruments with white reload on any tissue that requires excessive force to compress to 1.0 mm or on any tissue that compresses easily to below 1.0 mm.
- Do not use the instruments with blue reload on any tissue that requires excessive force to compress to 1.5 mm or on any tissue that compresses easily to below 1.5 mm.
- Do not use the instruments with green reload on any tissue that requires excessive force to compress to 2.0 mm or on any tissue that compresses easily to below 2.0 mm.
- Do not use the instruments on ischemic or necrotic tissue.
- Do not use the instruments on the aorta.
- Do not use any linear cutter on major vessels without making provision for proximal and distal control.
- Do not use the instruments on solid organs, such as the liver or spleen, where attempted compression would be destructive.
- These instruments are not intended for use when surgical stapling is contraindicated.

Device Descriptions

The ENDOPATH ETS45, ETS-Flex45, and ETS Compact-Flex45 Linear Cutters are sterile, single patient use instruments that deliver staples while simultaneously dividing tissue between rows. ETS45 instruments with blue (standard) reloads deliver two double- or triple- staggered rows of staples; ETS45 instruments with green (thick) reloads deliver two double-staggered rows of staples only; ETS45 instruments with white (vascular) reloads deliver two triple-staggered rows of staples. The instruments' safety lock-out feature is designed to prevent a used reload from being refired. The instruments have a staple line that is approximately 45 mm long and a cut line that is approximately 41 mm long. A staple retaining cap on the reload protects the staple leg points during shipping and transportation. An articulation lever on the ETS-Flex45 and ETS Compact-Flex45 Articulating Linear Cutters enables bilateral movement of the instrument jaws.

The ENDOPATH ETS-Flex45 and ETS Compact-Flex45 No-Knife Linear Staplers are sterile, single patient use instruments. ETS45 instruments with blue (standard) reloads deliver two double- or triple-staggered rows of staples; ETS45 instruments with green (thick) reloads deliver two double-staggered rows of staples only; ETS45 instruments with white (vascular) reloads deliver two triple-staggered rows of staples. The instruments' safety lock-out feature is designed to prevent a used reload from being refired. The instruments have a staple line that is approximately 45 mm long. A staple retaining cap on the reload protects the staple leg points during shipping and transportation. An articulation lever on the instruments enables bilateral movement of the instrument jaws.

The instruments are loaded with a vascular, white reload; a standard, blue reload; or a thick tissue, green reload. ETS45 reloads are interchangeable across all ETS45 family instrument codes. For example, a TSW45 instrument, which is provided with a TR45W reload, may be reloaded with either the TR45B, the TR45G, the TR45W, or the GR45B.

Do not reload the instruments more than seven times for a maximum of eight firings per instrument. The use of the instrument with staple line buttressing material may reduce the number of firings. Use only the indicated reloads in the ETS45 instrument. Do not use ETS45 family reloads in an instrument other than an ETS45 family instrument.

ETS45 Product Family

Instrument Code	Description	Shaft Length
TSW45	ETS45 Endoscopic Linear Cutter, Vascular	340 mm
TSB45	ETS45 Endoscopic Linear Cutter, Standard	340 mm
TSG45	ETS45 Endoscopic Linear Cutter, Thick Tissue	340 mm
6SB45	ETS45 Endoscopic Linear Cutter, Standard (6 Rows)	340 mm
ATW45	ETS-Flex45 Endoscopic Articulating Linear Cutter, Vascular	340 mm
ATB45	ETS-Flex45 Endoscopic Articulating Linear Cutter, Standard	340 mm
ATG45	ETS-Flex45 Endoscopic Articulating Linear Cutter, Thick Tissue	340 mm
6TB45	ETS-Flex45 Endoscopic Articulating Linear Cutter, Standard (6 Rows)	340 mm
SCW45	ETS Compact-Flex45 Endoscopic Articulating Linear Cutter, Vascular	240 mm
SCB45	ETS Compact-Flex45 Endoscopic Articulating Linear Cutter, Standard	240 mm
SCG45	ETS Compact-Flex45 Endoscopic Articulating Linear Cutter, Thick Tissue	240 mm
6CB45	ETS45 Compact-Flex45 Endoscopic Articulating Linear Cutter, Standard (6 Rows)	240 mm
NAW45	ETS-Flex45 No-Knife Articulating Linear Stapler, Vascular	340 mm

NAB45	ETS-Flex45 No-Knife Articulating Linear Stapler, Standard	340 mm
NAG45	ETS-Flex45 No-Knife Articulating Linear Stapler, Thick Tissue	340 mm
NSW45	ETS Compact-Flex45 No-Knife Articulating Linear Stapler, Vascular	240 mm
NSB45	ETS Compact-Flex45 No-Knife Articulating Linear Stapler, Standard	240 mm
NSG45	ETS Compact-Flex45 No-Knife Articulating Linear Stapler, Thick Tissue	240 mm
LONG45A	ETS-Flex45 Endoscopic Articulating Long Linear Cutter, No Reload	440 mm

Specifications for ETS45 family reloads follow:

Supported Instrument Codes: TSW45, TSB45, TSG45, ATW45, ATB45, ATG45, SCW45, SCB45, SCG45, NAB45, NAG45, NAW45, NSW45, NSB45, NSG45, LONG45A, 6SB45, 6TB45, 6CB45.

Reload Code	Description	Staple Leg Length	Closed Staple Height	Number of Staples	Reload Color	Staple Rows
TR45W	Vascular/Thin	2.5 mm	1.0 mm	66	White	6
TR45B	Standard	3.5 mm	1.5 mm	44	Blue	4
6R45B	Standard	3.5 mm	1.5 mm	66	Blue	6
TR45G	Thick	4.1 mm	2.0 mm	44	Green	4

Illustration and Nomenclature (Illustration 1)

- | | |
|----------------------------|----------------------------|
| 1. Closing Trigger (1) | 8. Reload Alignment Tab |
| 2. Firing Trigger (2) | 9. Staple Retaining Cap |
| 3. Rotating Knob | 10. Anvil Jaw |
| 4. Articulation Lever | 11. Cartridge Jaw |
| 5. Anvil Release Button | 12. Reload Alignment Notch |
| 6. Handle | 13. Articulation Joint |
| 7. Reload Gripping Surface | |

Instructions for Use

Verify compatibility of all instruments and accessories prior to using the instrument (refer to **Warnings and Precautions**).

Note: The following instruments cut and staple: TSW45, TSB45, TSG45, ATW45, ATB45, ATG45, SCW45, SCB45, SCG45, LONG45A, 6SB45, 6TB45, 6CB45. The following instruments perform stapling only: NAB45, NAG45, NAW45, NSW45, NSB45, NSG45.

- Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
- Remove the staple retaining cap from the reload. Discard the staple retaining cap. (Illustration 2)
Note: The staple retaining cap ensures proper staple orientation and protects the staple leg points during shipping and transportation.

- Note: The LONG45A instrument is not preloaded. Remove the protective cover from the tip of the instrument before loading the instrument (see **Reloading the Instrument**).
- 3 Close the jaws of the instrument by squeezing the closing trigger (light gray and labeled with a Number "1") until it locks in place. An audible click indicates that the closing trigger is locked. (Illustration 3)
Caution: Do not squeeze the firing trigger (dark gray and labeled with a Number "2") at this time.
 - 4 Introduce the instrument into the body cavity through the appropriate trocar or incision. (Illustration 4)
Caution: The instrument jaws must be closed to be introduced into the cavity through a trocar of the appropriate size.
 - 5 Once in the cavity, press the anvil release button to reopen the instrument jaws and return the closing trigger (1) to its original position. (Illustration 5)
 - 6 To articulate the instrument (articulating instruments only), turn the articulation lever until it comes to a stop in either direction. (Illustration 6)
Caution: Tissue damage or trauma may result if the instrument is articulated after closing on tissue.
Caution: Attempting to force the articulation lever beyond its stop in either direction will result in instrument damage.
 - 7 After positioning the instrument jaws around the tissue to be stapled, close the jaws by squeezing the closing trigger (1) toward the handle until it locks. An audible click indicates that the closing trigger is locked.
Caution: If the closing trigger (1) is difficult to lock, **reposition the instrument and take a smaller amount of tissue.** (See **Contraindications** for appropriate reload selection.)
Caution: Ensure that the tissue lies flat and is positioned properly between the jaws. Any "bunching" of tissue along the reload may result in an incomplete staple line.
 Note: The use of staple line buttressing materials with the instrument may require an increased force to close.
 - 8 Fire the instrument by squeezing the firing trigger (2) completely until it rests on the closing trigger (1). (Illustration 7)
Caution: The firing stroke must be completed. **Do not** partially fire the instrument.
 Note: The use of staple line buttressing materials with the instrument may require an increased force to fire and may reduce the number of firings.
 Note: Crossing of staple lines may shorten the life of the instrument.
 - 9 Relax grip. Press the anvil release button to separate the instrument jaws and allow the closing and firing triggers to return to their original positions (Illustration 8). Before removing the instrument, make sure that tissue is removed from the jaws.
Caution: After firing, examine the staple lines for pneumostasis/hemostasis and proper staple closure. If pneumostasis/hemostasis is not present, appropriate techniques should be used to achieve pneumostasis/hemostasis.
Caution: If the jaws do not automatically open after the anvil release button is pressed, pull the firing trigger (Number 2) upward (away from handle) until both firing and closing triggers return to their original positions. If the firing mechanism becomes inoperative, **do not** refire the instrument. (Remove and discard the instrument.)
 - 10 To remove the instrument from the cavity, squeeze the closing trigger (1) until it locks, closing the jaws. (Illustration 9) When removing the articulating instruments, the articulation lever must be straight, indicating that the jaws of the instrument are also straight.
Caution: Failure to have the instrument jaws in the straight position will result in difficult withdrawal of the instrument and may result in breakage. Failure to straighten the instrument prior to reloading may prevent proper function of the fired cartridge lockout mechanism.
 - 11 Completely withdraw the instrument in the closed position.

Reloading the Instrument

- 1 Using sterile technique, remove the reload from the package. To avoid damage, do not flip the reload into the sterile field.
- 2 Prior to reloading, ensure the instrument is in the open position. (Illustration 10)
- 3 Push upward (toward the anvil) to unsnap the reload from the cartridge jaw. Discard the used reload. (Illustration 11)
Caution: Clean any unused staples from the instrument by wiping the anvil and cartridge jaw or rinsing in sterile solution.
- 4 Examine the new reload for the presence of a staple retaining cap. If the retaining cap is not in place, discard the reload.
Note: Selection of the appropriate staple cartridge should be based upon the combined thicknesses of both the tissue and the staple line buttressing materials.
- 5 Insert the new reload by sliding it against the bottom of the cartridge jaw until it stops in the reload alignment slot. Snap the reload securely in place. Remove the staple retaining cap and discard. The instrument is now reloaded and ready for use. (Illustration 12)
Caution: After removing the staple retaining cap, observe the surface of the new reload. The reload must be replaced with another reload if any colored drivers are visible. (If colored drivers are visible, the reload may not contain staples.)

Warnings and Precautions

- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- Minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. Do not immerse electrosurgical instruments in liquid unless the instruments are designed and labeled to be immersed.
- When dividing major vascular structures, be sure to adhere to the basic surgical principle of proximal and distal control.
- Before using, remove the staple retaining cap and observe the surface of the reload. The reload must be replaced with another reload if any colored drivers are visible.
- Ensure that the tissue lies flat and is positioned properly between the jaws. Any "bunching" of tissue along the reload may result in an incomplete staple line.
- Prior to articulating and positioning the instrument jaws on tissue, make sure the jaws are in the open position.
- The firing stroke must be completed. Do not partially fire the instrument.
- Before removing the instrument, be sure tissue is cleared from the jaws and then close the jaws. Prior to removing the articulating instruments from the cavity, ensure the instrument is not articulated.
- After removing the instrument, examine the staple line for pneumostasis/hemostasis and proper staple closure. If pneumostasis/hemostasis is not present, appropriate techniques should be used to achieve pneumostasis/hemostasis.
- The instrument may be reloaded during a single procedure. Do not reload the instrument more than seven times for a total of eight firings per instrument.
- The firing trigger (2) and closing trigger (1) must be in the open position during reloading.
- If the jaws do not automatically open after the anvil release button is pressed, pull the firing trigger (Number 2) upward (away from handle) until both firing and closing triggers return to their original

positions. If the firing mechanism becomes inoperative, do not refire the instrument. (Remove and discard the instrument.)

- If the clamping mechanism becomes inoperative and the jaws do not clamp on tissue, do not fire the instrument. (Remove and discard the instrument and reload.)
- Crossing of staple lines may shorten the life of the instrument.
- When using a tissue or staple line buttressing material, the instructions of the manufacturer of the buttress material should be followed. The use of staple line buttressing materials with the instrument may require an increased force to fire and may reduce the number of firings.
- Selection of the appropriate staple cartridge should be based upon the combined thicknesses of both the tissue and the staple line buttressing materials.
- For removal of the articulating instruments, the articulation lever must be straight, indicating that the jaws of the instrument are also straight. Failure to have the instrument jaws in the straight position will result in difficult withdrawal of the instrument and may result in breakage. Failure to straighten the instrument prior to reloading may prevent proper function of the fired cartridge lockout mechanism.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- Dispose of all opened instruments and reloads whether used or unused.
- This device is packaged sterile in a protective pouch and is for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Also, reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

How Supplied

The ENDOPATH ETS45, ETS-Flex45, and ETS Compact-Flex45 Linear Cutters are supplied sterile for single patient use. Discard after use.

The ENDOPATH ETS-Flex45 and ETS Compact-Flex45 No-Knife Articulating Linear Staplers are supplied sterile for single patient use. Discard after use.

The reloads for use with the ENDOPATH ETS45, ETS-Flex45, and ETS Compact-Flex45 Linear Cutters are supplied sterile for single patient use. Discard after use.

The reloads for use with the ENDOPATH ETS-Flex45 and ETS Compact-Flex45 No-Knife Articulating Linear Staplers are supplied sterile for single patient use. Discard after use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

November 4, 2003

From: Reviewer(s) - Name(s) Herbert Lerner MD DKK

Subject: 510(k) Number K033 269

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) ✓

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

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

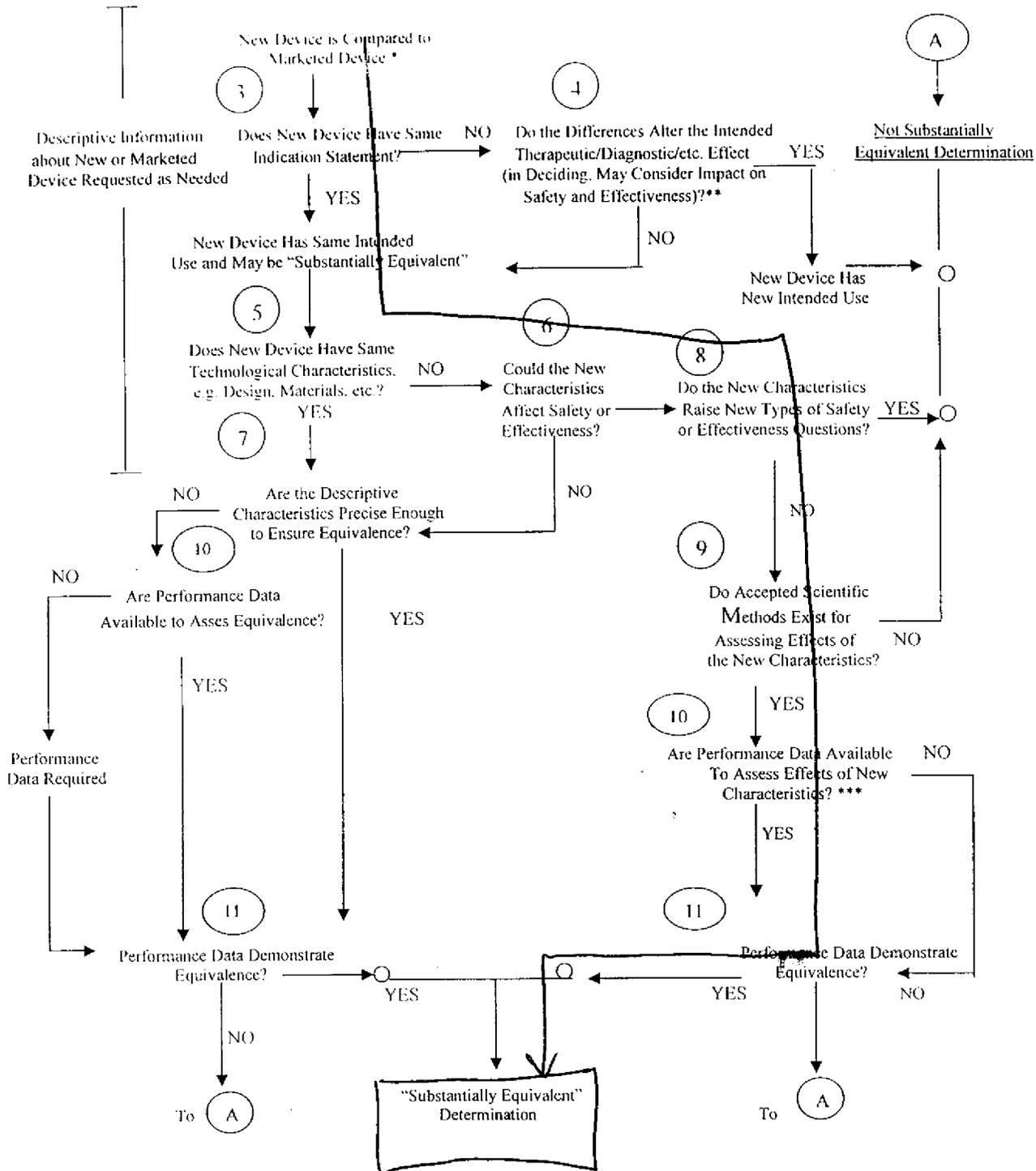
Predicate Product Code with class: Additional Product Code(s) with panel (optional):

K06 - 876.1500, Class II, Implantable Staple
ADW, 828-4250,

Review: Stuart Pluchis PRSB 11/25/03
(Branch Chief) (Branch Code) (Date)

Final Review: Miriam C. Provost 12/2/03
for (Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 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 maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Reviewer: Herbert Lerner MD
 Division/Branch: PRSB
 Device Name: Endopath Endocutter Gray Cartridge
 Product To Which Compared (510(K) Number If Known): Same (K020779)

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

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue: *Same device with a change in staple size*
5. Describe the new technological characteristics: *change in staple size*
6. Explain how new characteristics could or could not affect safety or effectiveness: *Proven safety of staples; data to support new design (size) of staple*
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new: *Same staple (+ stapler); just size change*
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed: *Functional performance data*
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent: *No change in efficiency of staple, no T risks involved.*

ATTACH ADDITIONAL SUPPORTING INFORMATION

510 (k) Memorandum
K033269

To: The Record
From: Herbert Lerner, MD
Date: October 28, 2003
Subject: Endopath Endocutter Gray Cartridge
Sponsor: Ethicon Endo-Surgery, Inc.
4545 Creek Rd.
Cincinnati, OH 45242-2839

Contact: Ms. Georgia C. Abernathy
513-337-3179

Predicates: Endopath Endocutter K020779, K002398, K980815, K961390, K935064
Procode: KOG, GDW
CFR: 876.1500, 878.4750

Recommendation: Substantially Equivalent

The device does not contain drugs or biologicals.

Indications:

The Endopath ETS45 Endoscopic Linear Cutter, the ETS-Flex45 Endoscopic Articulating Cutters, and the ETS Compact-Flex45 Articulating Cutters are intended for transaction, resection, and/or creation of anastomosis. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

The Endopath ETS45 No-Knife Articulating Linear Staplers and the ETS Compact-Flex45 No-Knife Articulating Linear Staplers are intended for transaction, resection, and/or creation of anastomosis. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic (including radical prostatectomy), thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials such as bovine pericardium.

The predicate devices are (b)(4),(b)(5) the size of the staple to a nominal closure height of 0.85mm. The predicates have nominal closed staple heights of 1.0 to 2.0mm.

The sponsor is adding this line of staple cartridges to accommodate different tissue thicknesses, and has not otherwise modified the device.

Technological Characteristics:

The Endopath Linear Cutters models are sterile, single use instruments that deliver staples while simultaneously dividing tissue between rows. The endopath No-Knife Staplers are sterile, single use instruments that deliver staples, but do not cut. Depending on the particular model, they deliver 2 to 3 staggered rows of staples, 2 double-staggered rows, or 2 triple-staggered rows of staples. Staple line lengths vary between 35mm and 100mm. These instruments may be used in open or endoscopic procedures. Some instruments are reloadable. Vascular models use specific vascular reload cartridges. All these instruments are mechanical surgical stapling devices. The cartridges, which are the subject of this 510 (k), are inserted onto the cutters or staplers to achieve the desired result.

Product Code	Color of Cartridge	Number of Rows	Nominal Closed Staple Height
6R45M (new)	Gray	6 row	0.85mm
TR45W	White	6 row	1.0mm
6R45B	Blue	6 row	1.5mm
TR45B	Blue	4 row	1.5mm
TR45G	Green	4 row	2.0mm

As stated above, the predicate and subject device are (b)(4),(b)(5)
(b)(4),(b)(5)

Performance Data:

(b)(4),(b)(5)

Again, as the devices are the same as the predicate with the staple size the only variant, these tests show equivalence and I have no issues with the safety or efficiency of the device.

Sterilization:

Method; Gamma radiation
Standard: ISO 11137-1994
Dose: 25 kGY
SAL: 10^{-6}
Packaging: (b)(4),(b)(5)

The device is sold by prescription only.

Labeling:

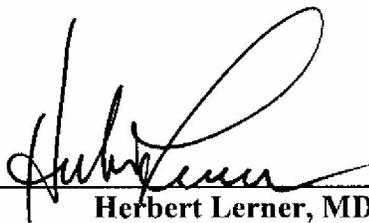
Draft Labels are provided for this device, actual labels for the predicate (similar) device.
Package Insert and labels- page 41-51

Administrative:

Truth and Accurate Statement- page 14
Indications for Use- page 14
510 (k) Summary- page 39

Summary:

The sponsor has presented this device as an extension of the already marketed line of Endopath stapling devices; the main difference is the size of the staples in this Gray Cartridge. Adequate bench and animal testing provided assurances of safety and efficiency and therefore the device is **substantially equivalent** to the predicates.



Herbert Lerner, MD

concur
mp 12/2/03

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?	N/A	
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?	✓	✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N/A	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	N/A	