



USER: COLMES, JERI R (jrc)

FOLDER: K050344 - 86 pages (FOI:06002317)

COMPANY: ETHICON ENDO SURGERY, INC.
(ETHIENDOSURGA)

PRODUCT: CLIP, IMPLANTABLE (FZP)

SUMMARY: Product: LIGACLIP 5 M/L MM ENDOSCOPIC
MULTIPLE CLIP APPLIER

DATE REQUESTED: Thu Feb 07 24:00:00 2008

DATE PRINTED: Wed Feb 27 13:35:23 2008

Note: Releasable Version

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Ethicon Endo-Surgery, Inc.
510(k) Premarket Notification for LIGACLIP® 5 M/L

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LIGACLIP® 5 M/L 510(k) Summary of Safety and Effectiveness

Company

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

MAR 14 2005

Contact

Kimberly Shoemaker
Manager, Regulatory Affairs

Date Prepared:

February 10, 2005

Name of Device

Trade Name: LIGACLIP® 5M/L Endoscopic Multiple Clip Applier
Classification Name: Implantable Clip

Predicate Devices:

Trade Name: LIGACLIP® ERCA Endoscopic Rotating Multiple Clip Applier
Cleared under 510(k) numbers K0864102 on November 5, 1986. The Titanium Clips used with the applier were cleared March 9, 1983 under K830503.

Device Description

The LIGACLIP® 5 M/L Endoscopic Multiple Clip Applier is a sterile, single patient use, disposable surgical instrument designed to provide a means of ligation through an appropriately sized trocar. The instrument configuration consists of a pistol grip handle, an actuation trigger, a rotation knob, a shaft having an outer diameter of 5.5mm and a length of 33cm. At the distal end of the shaft is a set of jaws for forming ligating clips. The device contains 15 clips.

Indications for Use

The LIGACLIP® 5 M/L 5 mm Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated. The tissue being ligated should be consistent with the size of the clip.

Ethicon Endo-Surgery, Inc.
510(k) Premarket Notification for LIGACLIP[®] 5 M/L

K050344 Page 2/2

Technological Characteristics

The LIGACLIP[®] 5 M/L 5 mm Endoscopic Multiple Clip Applier is identical to the predicate device with respect to intended use. The device is operated in a manner similar to the predicate device.

Performance Data

Bench testing was performed to ensure that the device performs as intended. All testing results demonstrated satisfactory performance.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 14 2005

Ms. Kimberly Shoemaker
Manager, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K050344

Trade/Device Name: LIGACLIP® 5M/L 5mm Endoscopic Multiple Clip Applier
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: FZP
Dated: February 10, 2005
Received: February 11, 2005

Dear Mr. Shoemaker:

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.

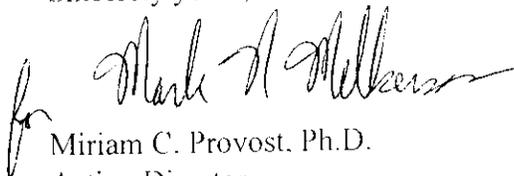
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 - Ms. Kimberly Shoemaker

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark A. Melker". The signature is written in a cursive style and is positioned to the right of a small, stylized "for" symbol.

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 14 2005

Ms. Kimberly Shoemaker
Manager, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K050344

Trade/Device Name: LIGACLIP[®] 5M/L 5mm Endoscopic Multiple Clip Applier
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
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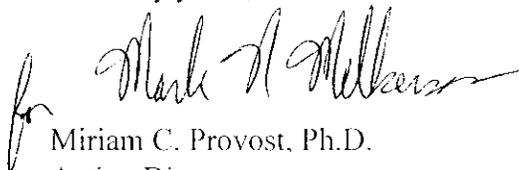
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Page 2 - Ms. Kimberly Shoemaker

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Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark A. Milken". To the left of the signature is a small, stylized initial "for".

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

February 11, 2005

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 ROAD
 CINCINNATI, OH 45242
 ATTN: KIMBERLY SHOEMAKER

510(k) Number: K050344
 Received: 11-FEB-2005
 Product: LIGACLIP 5 M/L MM
 ENDOSCOPIC MULTIPLE
 CLIP APPLIER

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.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

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 regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>". 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

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K050344



ETHICON ENDO-SURGERY, INC.

a Johnson & Johnson company

4545 CIRCLE ROAD
CINCINNATI, OH 45224-2839

February 10, 2005

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation

**Re: 510(k) Premarket Notification
LIGACLIP® 5 M/L 5 mm Endoscopic Multiple Clip Applier**

Dear Sir or Madam:

This is to notify you of the intent of Ethicon Endo-Surgery, Inc. to market the LIGACLIP® 5 M/L 5 mm Endoscopic Multiple Clip Applier. LIGACLIP® 5 M/L is a sterile, single patient use instrument designed to provide a means of ligation through an appropriately sized trocar. The device is similar in function and intended use as the currently marketed LIGACLIP® ERCA Endoscopic Rotating Multiple Clip Applier based upon the LIGACLIP Multiple Clip Applier cleared November 5, 1986 under K864102. The Titanium Clips used with the applier were cleared March 9, 1983 under K830503.

A unique payment identification number (PIN) has been assigned to this submission: 017000-956733. A copy of the Medical Device User Fee Cover Sheet has been included in Section A, after the CDRH Submission Cover Sheet, for your convenience.

All information necessary for a substantial equivalence determination is included herein. Please contact me at (513) 337-8123, or Dennis Hahn at (513) 337-3134, if you have any questions during the review of this submission.

Sincerely,

Kimberly Shoemaker, RAC
Manager, Regulatory Affairs

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Ethicon Endo-Surgery, Inc.
510(k) Premarket Notification for LIGACLIP® 5 ML

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

Ethicon Endo-Surgery, Inc.
510(k) Premarket Notification for LIGACLIP® 5 M/L

Section A

CDRH Submission Cover Sheet

A completed CDRH Submission Cover Sheet is provided in the following pages.

20 3

Ethicon Endo-Surgery, Inc.
510(k) Premarket Notification for LIGACLIP® 5 M/L.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: September 30, 2004.
See OMB Statement on page 5.

Date of Submission
2/8/2005

User Fee Payment ID Number
(b) (4)

FDA Submission Document Number (if known)

SECTION A

TYPE OF SUBMISSION

<p>PMA</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<p>PMA & HDE Supplement</p> <input type="checkbox"/> Regular (120 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <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 & HDE Supplement <input type="checkbox"/> Other	<p>PDP</p> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<p>510(k)</p> <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<p>Meeting</p> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
<p>IDE</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<p>Humanitarian Device Exemption (HDE)</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<p>Class II Exemption Petition</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p>Evaluation of Automatic Class III Designation (De Novo)</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p>Other Submission</p> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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

SECTION B

SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Ethicon Endo-Surgery, Inc.		Establishment Registration Number (if known) 1527736	
Division Name (if applicable)		Phone Number (including area code) (513) 337-8123	
Street Address 4545 Creek Road		FAX Number (including area code) (513) 337-1444	
City Cincinnati	State / Province Ohio	ZIP/Postal Code 45242	Country USA
Contact Name Kimberly Shoemaker			
Contact Title Manager, Regulatory Affairs		Contact E-mail Address kshoema1@eesus.jnj.com	

Ethicon Endo-Surgery, Inc.
 510(k) Premarket Notification for LIGACLIP® 5 M/L

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

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

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

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below) Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<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"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<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"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (specify):		

Ethicon Endo-Surgery, Inc.
 510(k) Premarket Notification for LIGACLIP® 5 M/L

SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <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"/> Continued Access <input type="checkbox"/> Request for Removal of Applicant Hold	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing 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 Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Reponse 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 <input type="checkbox"/> Request Hearing <div style="text-align: right; margin-right: 20px;">Manufacturer</div>			
<input type="checkbox"/> Other Reason (specify):					
SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology	<input type="checkbox"/> Other Reason (specify):		

Ethicon Endo-Surgery, Inc.
510(k) Premarket Notification for LIGACLIP® 5 M/L

SECTION E		ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS			
Product codes of devices to which substantial equivalence is claimed					
1	FZP	2	3	4	Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
5		6	7	8	

Information on devices to which substantial equivalence is claimed (if known)					
510(k) Number	Trade or Proprietary or Model Name	Manufacturer			
1	K864102	2	LIGACLIP ERCA Endoscopic Multiple Clip Applier (M, M/L, L)	2	Ethicon Endo-Surgery, Inc.
2	K830503	3	LIGACLIP® Titanium Ligating Clip Applier and Clip Cartridge	3	Ethicon Endo-Surgery, Inc.
3					
4		4		4	
5		5		5	
6		6		6	

SECTION F **PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification
VARIOUS TYPES OF STERILE AND NON-STERILE LIGATING CLIPS AND APPLIERS

Trade or Proprietary or Model Name for This Device	Model Number
1 LIGACLIP® 5 M/L	1 EL5ML
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome)					
1	2	3	4	5	6
K864102	K830503				
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

24 7

Ethicon Endo-Surgery, Inc.
 510(k) Premarket Notification for LIGACLIP® 5 M/L

SECTION G				PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS			
Product Code FZP		C.F.R. Section (if applicable) 21 CFR 878.4300		Device Class			
Implantable Clip		Classification Panel		<input type="checkbox"/> Class I		<input checked="" type="checkbox"/> Class II	
				<input type="checkbox"/> Class III		<input type="checkbox"/> Unclassified	
Indications (from labeling) The LIGACLIP® 5 M/L 5 mm Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated. The tissue being ligated should be consistent with the size of the clip.							
Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.				FDA Document Number (if known)			
SECTION H							
MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION							
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number 9710649		<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, SA de C.V. Plant II				Establishment Registration Number 9710649			
Division Name (if applicable) \				Phone Number (including area code) (915) 791-3239			
Street Address Boulevard Independencia #1151 Lote Bravo				FAX Number (including area code) ()			
City Cd. Juarez		State / Province Chih		ZIP Code		Country Mexico	
Contact Name Dave Kouchoukos		Contact Title Quality Systems Manager		Contact E-mail Address dkouchou@eesus.jnj.com			

Ethicon Endo-Surgery, Inc.
 510(k) Premarket Notification for LIGACLIP® 5 M/L

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number 1628808		<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Sterilizer <input checked="" 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 (including area code) (915) 791-3419		
Street Address 3801 University Boulevard., S.E.			FAX Number (including area code) ()		
City Albuquerque		State / Province NM	ZIP Code 87106	Country USA	
Contact Name Nancy Amaya		Contact Title Quality Systems Manager		Contact E-mail Address namaya@eesus.jnj.com	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) ()		
Street Address			FAX Number (including area code) ()		
City		State / Province	ZIP Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

Form Approved OMB No. 0910-0511 Expiration Date: August 31, 2006. See instructions for OMB Statement.

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

PAYMENT IDENTIFICATION NUMBER: (b) (4)

Write the Payment Identification Number on your check.

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

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

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

ETHICON ENDO-SURGERY, INC.
 4545 CREEK ROAD
 CINCINNATI, OH 45242-2839

2. CONTACT NAME
 KIMBERLY SHOEMAKER

2.1 E-MAIL ADDRESS
 kshoema1@eesus.jnj.com

2.2 TELEPHONE NUMBER (Include Area Code)
 513-337-8123

2.3 FACSIMILE (FAX) NUMBER (Include Area Code)
 513-337-1444

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
 340832179

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

Select an application type:

- Premarket notification (510(k)); except for third party reviews
- Biologics License Application (BLA)
- Premarket Approval Application (PMA)
- Modular PMA
- Product Development Protocol (PDP)
- Premarket Report (PMR)

3.1 Select one of the types below:

- Original Application

Supplement Types:

- Efficacy (BLA)
- Panel Track (PMA, PMR, PDP)
- Real-Time (PMA, PMR, PDP)
- 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.)

YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

- This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
- This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

- The sole purpose of the application is to support conditions of use for a pediatric population
- The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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

YES NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)

(b) (4)

Form FDA 3601 (08/2003)

Ethicon Endo-Surgery, Inc.
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Section B

Reviewer's Screening Checklist

The Reviewer's Screening Checklist for completing a 510(k) Premarket Notification is provided in the following pages.

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**SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: _____

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

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

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

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510(k)] Manual.	Page 1	
Table of Contents.	Page 2	
Truthful and Accurate Statement.	Section K	
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(k)] Manual.	Section E	
Statement of Indications for Use that is on a separate page in the premarket submission.	Section J	
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(k)] Manual.	Section D	
510(k) Summary or 510(k) Statement.	Section L	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	Section C	
Identification of legally marketed predicate device. *	Section A	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	N/A ¹	
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	

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- † - 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 submitter'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 submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
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.		

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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 Required Elements for a Declaration of Conformity to a Recognized Standard , which is posted with the 510(k) boilers on the H drive .]		
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.

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 510(k) Premarket Notification for LIGACLIP® 5 M/L

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 H	
b) Sterilization and expiration dating information:	Section I	
i) sterilization process	Section I	
ii) validation method of sterilization process	Section I	
iii) SAL	Section I	
iv) packaging	Section I	
v) specify pyrogen free	N/A ¹	
vi) ETO residues	Section I	
vii) radiation dose	N/A ¹	
viii) Traditional Method or Non-Traditional Method	N/A ¹	
c) Software Documentation:	N/A ¹	

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" 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.htm>

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Section C

Device Description

A detailed description of the LIGACLIP[®] 5 M/L device is provided in the following pages.

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Device Description

General Description:

The LIGACLIP[®] 5 M/L Endoscopic Multiple Clip Applier is a sterile, single patient use, disposable surgical instrument designed to provide a means of ligation through an appropriately sized trocar. The instrument configuration consists of a pistol grip handle, an actuation trigger, a rotation knob, a shaft having an outer diameter of 5.5mm and a length of 33cm. At the distal end of the shaft is a set of jaws for forming ligating clips.

The instrument contains 15 medium-large titanium clips for occluding tissue, structures, and vessels ranging in size from 1mm to 5mm in diameter. The clip design features a traditional barn shape with an embossed pattern on the inside perimeter for securing the clip onto targeted structures or vessels. The clip has an unformed aperture of 3.6mm and a formed length of 8.8mm. The formed clip length is identical to the marketed device, LIGACLIP ERCA.

The instrument is operated in a similar manner as the marketed device. The instrument jaws passively collapse upon entering the trocar cannula and fully reopen once beyond the distal end of the cannula. The jaws do not have sharp edges or other features that could inadvertently damage tissue or tear trocar gaskets. A clip is fed into the jaws through actuation of the trigger. Clip feeding is complete when the trigger is partially squeezed to the first audible click. The clip and jaws are then placed over the targeted structure or vessel. The shaft can rotate 360 degrees by means of the rotation knob to facilitate visualization and enable access to the targeted site. Continued actuation of the trigger begins to form the clip. The distal tips of the clip close first to capture the targeted structure or vessel. Ligation is achieved with full trigger closure, which is identified by fully squeezing the trigger against the handle. The trigger automatically reopens when released and the instrument is ready for the next clip application.

Indications for Use:

Indications: The LIGACLIP[®] 5 M/L Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated. The tissue being ligated should be consistent with the size of the clip.

Contraindications: Do not use the instrument for contraceptive tubal occlusion. Do not use the instrument on tissue, structures, or vessels upon which metal ligating clips would not be indicated.

Note: The above indications and contraindications are identical to the marketed device.

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Device Drawings:

Refer to the rendered CAD drawings of the LIGACLIP[®] 5 M/L Endoscopic Multiple Clip device and titanium clips in the following pages.

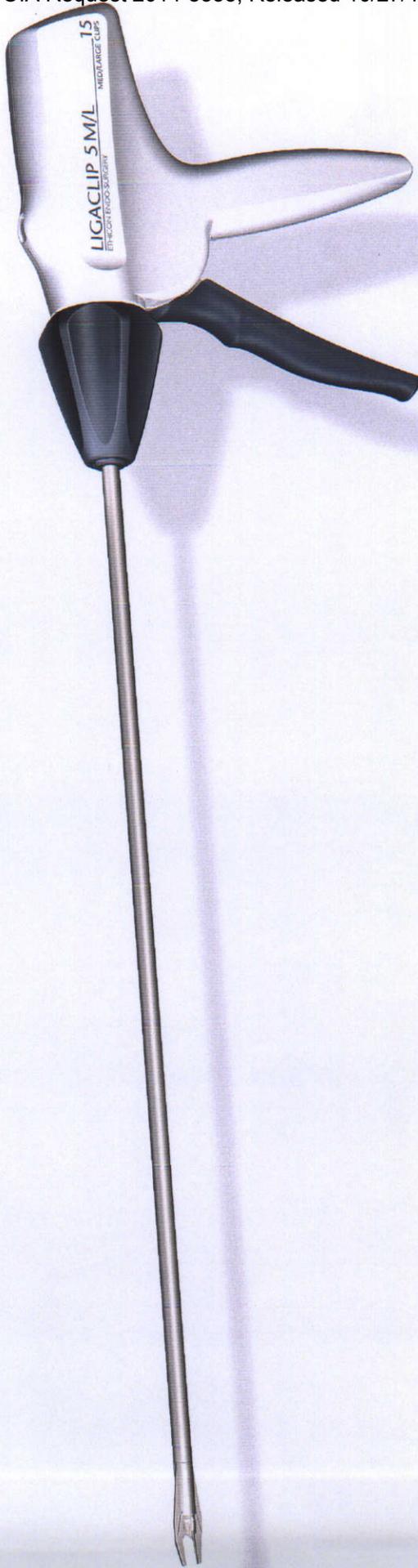
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LIGACLIP® 5 M/L

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LIGACLIP® 5 M/L



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Engineering Drawings:

Refer to engineering drawings for the LIGACLIP[®] 5 M/L Endoscopic Multiple Clip, Product Code EL5ML, Part Number D12840 and the LIGACLIP[®] ERCA marketed device, Product Code ER320, Part Number D00898 in the following pages.

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Section D

Substantial Equivalence

To facilitate a finding of substantial equivalence, the decision-making process provided for in the "510(k) Substantial Equivalence Decision-Making Process (Detailed)" (Blue Book Memorandum K86-3, 1986) is followed. The decision-making chart, with the path applicable to this submission highlighted, is provided in Appendix E-1. A side-by-side comparison of the proposed device to the legally marketed device is provided in Appendix E-2.

New Device is Compared to Marketed Device

New device:

LIGACLIP[®] 5 M/L 5 mm Endoscopic Multiple Clip Applier: product code EL5ML

Marketed device:

LIGACLIP[®] ERCA Endoscopic Rotating Multiple Clip Applier based upon the LAGACLIP Multiple Clip Applier cleared November 5, 1986 under K864102
The Titanium Clips used with the applier were cleared March 9, 1983 under K830503.

Does the Device Have Same Indication Statements?

Yes. The Indications for Use statement is identical.

The LIGACLIP[®] 5 M/L 5 mm Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated. The tissue being ligated should be consistent with the size of the clip.

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

No. There have been minor design changes. Refer to Section D, Appendix D-2 for a side by side comparison listing the differences/changes.

Could the new characteristics affect safety or effectiveness?

Yes. Minor design changes could affect safety or effectiveness.

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

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No, the new characteristics do not raise new types of safety or effectiveness questions.

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

Yes. Test methods exist for assessing functionality. Refer to Section G, Performance Testing.

Are performance data available to assess effects of new characteristics?

Yes. Testing was performed to ensure that the new characteristics perform equivalently. Refer to Section G, Performance Testing.

Performance data demonstrate equivalence?

Yes. The device performs equivalently.

Substantially Equivalent Determination

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Appendix D-1

Substantial Equivalence Decision-Making Flow Chart

The substantial equivalence decision-making flow chart is on the following page.

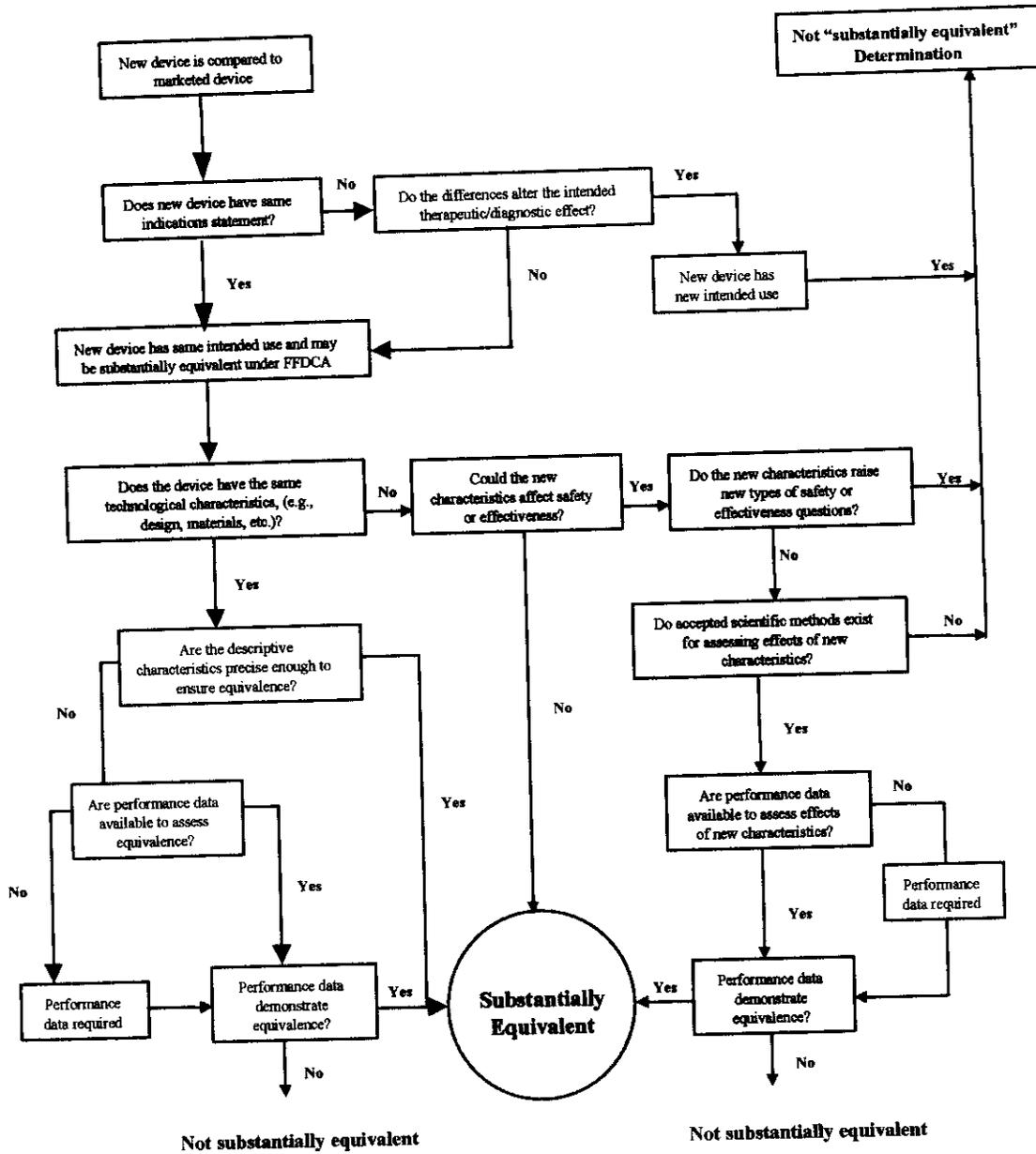
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510(k) "Substantial Equivalence" Decision Making Process



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Appendix D-2

Side-by Side Comparison to Legally Marketed Device

A side-by-side comparison of the proposed (new) and marketed devices is in the following pages.

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 510(k) Pre-market Notification for LIGACLIP® 5 M/L; Product Code EL5ML

	LIGACLIP® 5 M/L Product Code: EL5ML	LIGACLIP® ERCA Product Code: ER320
SIMILARITIES:		
Indications for Use	<ul style="list-style-type: none"> The instrument is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated. The tissue being ligated should be consistent with the size of the clip. 	<ul style="list-style-type: none"> Identical
Contraindications	<ul style="list-style-type: none"> DO NOT use the instrument for contraceptive tubal occlusion. DO NOT use the instrument on tissue structures or vessels upon which metal ligating clips would not normally be used. 	<ul style="list-style-type: none"> Identical Identical
Description	<ul style="list-style-type: none"> Sterile Single patient use Disposable 	<ul style="list-style-type: none"> Identical Identical Identical
Sterilization Process	<ul style="list-style-type: none"> Gamma or Ethylene Oxide 	<ul style="list-style-type: none"> Identical
Handle and Trigger	<ul style="list-style-type: none"> Conventional pistol-grip configuration with actuation trigger. 	<ul style="list-style-type: none"> Identical
Shaft Rotation	<ul style="list-style-type: none"> Smooth, 360-degree rotation in either direction. 	<ul style="list-style-type: none"> Similar; Indexed 360-degree rotation in either direction.
Clip Indicator	<ul style="list-style-type: none"> Indicator becomes progressively more visible when 3 or fewer clips remain in the device. 	<ul style="list-style-type: none"> Identical
Last Clip Lockout	<ul style="list-style-type: none"> The instrument contains a last clip lockout safety feature. The trigger cannot be easily squeezed shut once the last clip has been fired to prevent empty jaws from closing on a structure or vessel. 	<ul style="list-style-type: none"> Identical
Anti-backup Ratchet	<ul style="list-style-type: none"> The instrument contains an anti-backup feature that does not allow the trigger to reopen until clip formation is essentially complete. This prevents a partially formed clip from being displaced or falling from the jaw if the trigger is released prior to completion of the stroke. 	<ul style="list-style-type: none"> Identical
Clip Material	<ul style="list-style-type: none"> (b) (4) 	<ul style="list-style-type: none"> (b) (4)
Clip Closed Length	<ul style="list-style-type: none"> 8.8mm 	<ul style="list-style-type: none"> Identical
Basic Clip Geometry	<ul style="list-style-type: none"> Traditional Barn-Style Unformed Geometry 	<ul style="list-style-type: none"> Identical
Basic Clip Pattern	<ul style="list-style-type: none"> Transverse and lateral grooves with tongue and groove feature near apex 	<ul style="list-style-type: none"> Similar; Transverse and lateral grooves

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	LIGACLIP [®] 5 M/L Product Code: EL5ML	LIGACLIP [®] ERCA Product Code: ER320
DIFFERENCES:		
Entry into a trocar cannula	<ul style="list-style-type: none"> The jaws must be empty prior to inserting the device into a trocar cannula. The empty jaws will passively collapse as they pass through a 5mm trocar cannula and will reopen completely once beyond the distal end of the cannula. 	<ul style="list-style-type: none"> The jaws have a clip present when inserting the device into a 10mm trocar cannula. There is no need for the jaws to collapse, as the outer diameter of the device shaft is the same size as the jaw width.
Feed/Form Sequencing	<ul style="list-style-type: none"> The device is ready for use upon removal from the package. Clip feeding occurs during the early stages of trigger actuation at a rate determined by the user. Clip feeding is complete when the trigger is partially squeezed to the first audible click. Clip formation takes place during the middle and latter stages of trigger actuation following completion of clip feeding. Clip formation is completed when the trigger is fully squeezed against the handle. 	<ul style="list-style-type: none"> Upon removal from the package, the device must be actuated once to load a clip into the jaw in preparation for clip formation. Clip formation begins immediately during trigger actuation and proceeds throughout the trigger closure stroke. Clip formation is completed when the trigger is fully squeezed against the handle. Clip feeding occurs automatically upon release of the trigger. A clip is spring-fed into the jaw during the final stages of releasing the trigger.
Withdrawal from a trocar cannula	<ul style="list-style-type: none"> The jaws must be empty prior to withdrawing the device from a trocar cannula. The empty jaws will passively collapse as they pass through the trocar cannula and will reopen completely once beyond the proximal end of the cannula. 	<ul style="list-style-type: none"> The jaws have a clip present when withdrawing the device from the trocar cannula.
Jaw Clamping Force	<ul style="list-style-type: none"> Overload mechanism limits clamping forces based on jaw opening to protect instrument. 	<ul style="list-style-type: none"> Clamping forces are only limited by user grip strength and compliance of instrument components.
Shaft Diameter	<ul style="list-style-type: none"> 5.5mm outer diameter 	<ul style="list-style-type: none"> 10mm outer diameter
Overall Shaft Length	<ul style="list-style-type: none"> 33cm 	<ul style="list-style-type: none"> 29cm
Number of Clips	<ul style="list-style-type: none"> 15 clips 	<ul style="list-style-type: none"> 20 clips
Clip Aperture	<ul style="list-style-type: none"> 3.6mm 	<ul style="list-style-type: none"> 4.2mm
Clip Cross Section Geometry	<ul style="list-style-type: none"> 0.75mm wide x 0.50mm thick 	<ul style="list-style-type: none"> 1.1mm wide x 0.50mm thick
Clip Indicator Location	<ul style="list-style-type: none"> Indicator located inside top portion of handle assembly. 	<ul style="list-style-type: none"> Indicator located in shaft distal tip.

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510(k) Pre-market Notification for LIGACLIP[®] 5 M/L; Product Code EL5ML.

Section E

Draft Labeling

Draft Instruction for Use and labels for the proposed device are included in this section.

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510(k) Pre-market Notification for LIGACLIP[®] 5 M/L; Product Code EL5ML

LIGACLIP[®] 5 M/L 5 mm Endoscopic Multiple Clip Applier
Package Insert

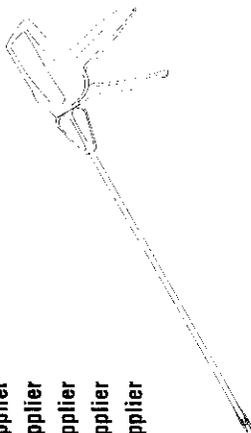
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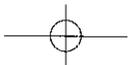
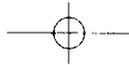
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LIGACLIP® 5 M/L

- 5 mm Endoscopic Multiple Clip Applier



- 5 mm Endoscopic Multiple Clip Applier



Please read all information carefully.

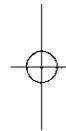
Failure to properly follow the instructions may lead to serious surgical consequences, such as failure to ligate.

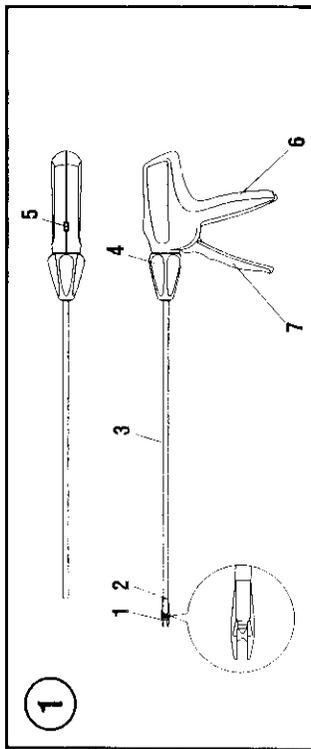
Important: This package insert is designed to provide instructions for use of the LIGACLIP® 5 M/L - 5 mm Endoscopic Multiple Clip Applier. It is not a reference to ligation techniques.



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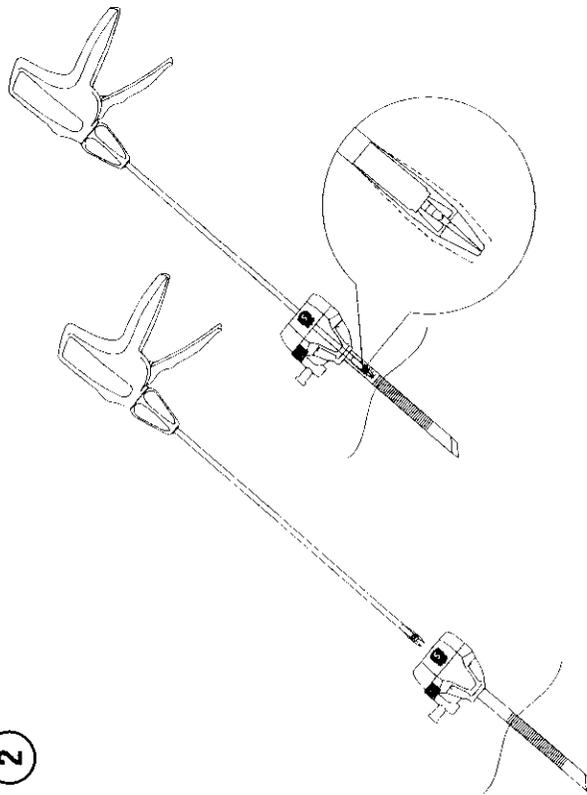
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 Utasítások, Navod k pouziti, Navod, 説明書



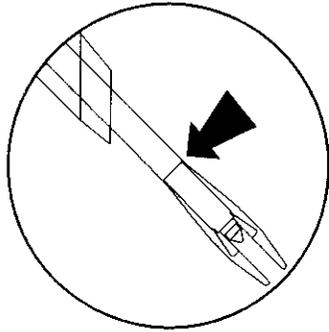


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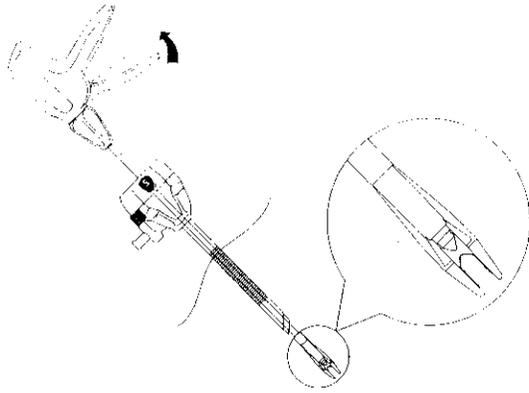
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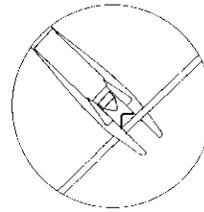
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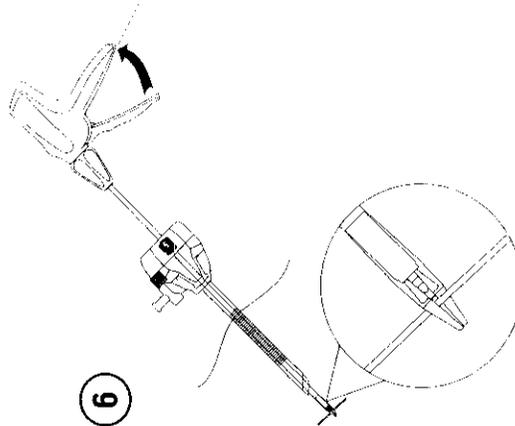
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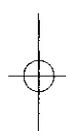
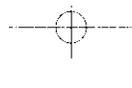
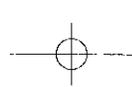


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3



English

Indications
The 5 mm Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated. The tissue being ligated should be consistent with the size of the clip.

Contraindications

- DO NOT use the instrument for contraceptive tubal occlusion.
- DO NOT use the instrument on tissue structures or vessels upon which metal ligating clips would not normally be used.

Device Description
The 5 mm Endoscopic Multiple Clip Applier is a sterile, single patient use instrument designed to provide a means of ligation through an appropriately-sized trocar. The instrument contains 15 titanium clips and the shaft can be rotated 360 degrees in either direction.

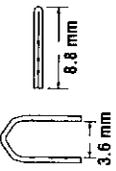
Product Code	Shaft Diameter	Clip Size/ No. of Clips	Clip Dimensions	Overall Shaft Length (approx.)
EL5ML	5.5 mm	Medium/Large 15		33 cm

Illustration and Nomenclature (Illustration 1)

- Jaws
- Demarcation
- Shaft
- Rotation Knob
- Indicator Window
- Handle
- Trigger

Instructions For Use

- Verify compatibility of all instruments and accessories prior to using the instrument (refer to **Warnings and Precautions**).
- Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
 - Remove the protective sleeve from the shaft of the instrument and discard.
 - Insert the clip applier through an appropriately-sized trocar. The empty jaws will passively collapse as they pass through a 5 mm trocar and reopen when completely through the trocar. (Illustration 2)
Caution: Do not insert the clip applier through a trocar if a clip is present in the jaws. This may result in clip malformation, dislodged clips, or damage to the instrument. If a clip is present in the jaws, fully squeeze the trigger against the handle, then fully release the trigger to release the clip from the jaws.
 - Prior to loading a clip in the jaws, ensure that the demarcation between the jaws and the instrument shaft is past the end of the trocar cannula. (Illustration 3)
 - Prior to positioning the jaws around the tubular structure or vessel, load a clip into the jaws by partially squeezing the trigger to the first audible click.
Caution: Inspect the jaw tips to ensure the clip is fully advanced in the jaws. (Illustration 4)
 - Position the jaws with the clip completely around the tubular structure or vessel to be ligated. The structure to be ligated should be positioned abutting the apex of the clip. (Illustration 5)
Note: The shaft can be rotated 360 degrees to facilitate visualization and accurate placement. Fully squeeze the trigger until it stops against the handle to completely form the clip on the targeted structure or vessel. (Illustration 6)
Caution: The trigger must be fully squeezed against the handle to ensure complete clip formation.
 - After firing, fully release the trigger.

Note: A clip will not be loaded in the jaws until the trigger is squeezed again. Check to ensure that each clip has been securely placed around the tissue being ligated.
Note: If a clip is present in the jaws and the clip applier needs to be removed from the patient, fully squeeze and hold the trigger against the handle while removing the clip applier through the trocar with the jaws in the closed position. Once the clip applier is removed, fully release the trigger to release the clip from the jaws. The clip applier is then ready for the next clip application.
Note: If a clip is dislodged prematurely from the jaw tips or a clip fails to advance, remove the jaws from the targeted structure and fully squeeze and release the trigger to reset the device. Continue to use the instrument as noted in step 5.

10 The 5 mm Endoscopic Multiple Clip Applier can be used to secure a catheter for cholangiography. During closure on the cystic duct and catheter, release the trigger after hearing the final audible click, prior to the trigger stopping against the handle.

11 When three clips or fewer remain in the clip applier, an orange bar will begin to appear in the indicator window on top of the device handle. The clip applier is empty when the orange bar completely fills the indicator window.

Note: The instrument contains a last clip lockout safety feature to prevent the empty jaws from closing on a structure or vessel. The trigger cannot be easily squeezed shut once the last clip has been fired.

12 To remove the instrument, ensure there is no clip remaining in the jaws, and withdraw the instrument from the trocar.

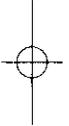
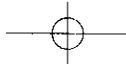
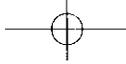
Warnings and Precautions

- 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, electrocautery, 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 electrocautery instruments in liquid unless the instruments are designed and labeled to be immersed.
- Ensure that the clip is the correct size for the vessel or tubular structure being ligated.
- Do not insert the clip applier through a trocar if a clip is present in the jaws. This may result in clip malformation, dislodged clips, or damage to the instrument. If a clip is present, fully squeeze the trigger against the handle, then fully release the trigger to release the clip from the jaws.
- Inspect the jaw tips to ensure the clip is fully advanced in the jaws.
- Ensure that each clip is securely and completely positioned around the tissue being ligated.
- Do not excessively twist or torque the instrument jaws when positioning or firing the instrument on a tubular structure or vessel. Excessive twisting or torquing may result in clip malformation.
- Do not excessively apply a side load to the jaws that would cause them to partially collapse and potentially result in a clip malformation. The device jaws should be fully open and parallel upon initiating the firing of the instrument.
- Do not push with excessive force on the proximal end of the instrument. Excessive force may result in clip malformation.
- The trigger must be fully squeezed against the handle to ensure complete clip formation.
- Ensure full release of the trigger after firing. A partial release of the trigger may disrupt clip feeding sequence and may result in clip malformation.
- Avoid firing the instrument over another clip or instrument. Firing the instrument in this manner may distort or yield the instrument jaws, which can cause the instrument to release the clip prematurely.
- Excessive tissue manipulation with clip in jaws may result in clip dislodgement.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.

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 LIGACLIP® 5 M/L - 5 mm Endoscopic Multiple Clip Applier is supplied sterile for single patient use. Discard after use.



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Ethicon Endo-Surgery, Inc.

510(k) Pre-market Notification for LIGACLIP[®] 5 M/L; Product Code EL5ML

LIGACLIP[®] 5 M/L 5 mm Endoscopic Multiple Clip Applier

Draft Labeling

Package Component Copy

Sales Label – Multilingual

1 LIGACLIP 5mm Endoscopic Multiple Clip Applier
Product Code: EL5ML

CONTENTS: One instrument designed for single patient use.

Sterilized Cobalt 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

©ETHICON ENDO-SURGERY, INC. 2004, Cincinnati, Ohio 45242-2839 USA

P4XXX89PXX

Assembled in Mexico

K05XXXX_EL5ML

February 10, 2005

55 28

Ethicon Endo-Surgery, Inc.

510(k) Pre-market Notification for LIGACLIP[®] 5 M/L; Product Code EL5ML

Section F

Marketed Device Labeling

Labeling for the marketed LIGACLIP[®] ERCA Endoscopic Rotating Multiple Clip Applier (ER320) device is provided in the following pages.

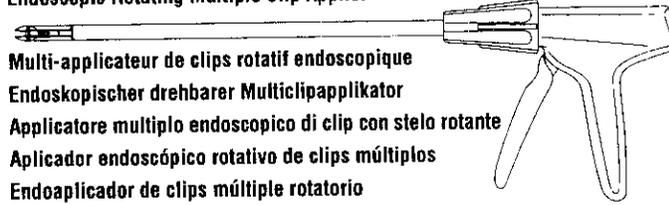
K05XXXX_EL5ML

February 10, 2005

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LIGACLIP® ERCA

Endoscopic Rotating Multiple Clip Applier



Multi-applicateur de clips rotatif endoscopique

Endoskopischer drehbarer Multiclipapplikator

Applicatore multiplo endoscopico di clip con stelo rotante

Aplicador endoscópico rotativo de clips múltiples

Endoaplicador de clips múltiple rotatorio

Endoscopische roterende multiple cliptang

Endoskopisk roterbar multiclipstang

Endoskoopinen kääntyvä ligeerausinstrumentti

Ενδοσκοπική περιστρεφόμενη λαβίδα απολίωσης πολλαπλών κλιπ

Endoskopisk roterbar multicliptång

Endoskopowa obrotowa wielokrotna klipsownica

Endoszkópiás forgó többszörös kapocsrakó

Multifunkční endoskopický aplikátor svorek

Endoskopický otočný viacúčelový aplikátor svoriek

リガクリップ* ERCA

内視鏡手術用クリップアプライヤー (連発式ローテートシャフト)

Please read all information carefully.

Failure to properly follow the instructions may lead to serious surgical consequences such as failure to ligate.

Important: This package insert is designed to provide instructions for use of the LIGACLIP® ERCA Endoscopic Rotating Multiple Clip Applier. It is not a reference to ligation techniques.

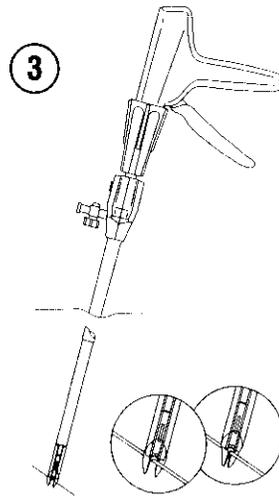
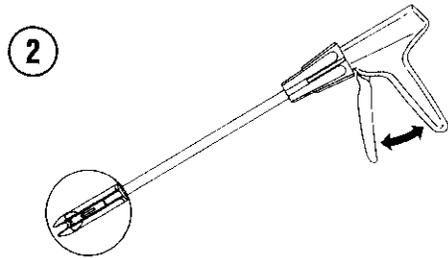
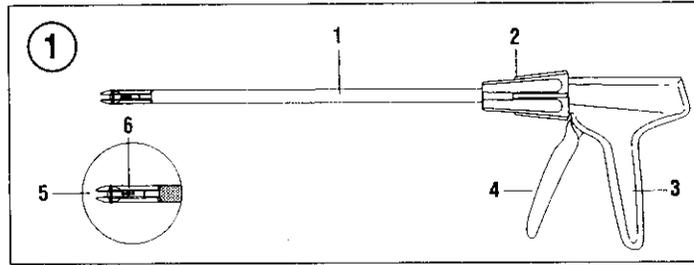


ETHICON ENDO-SURGERY, INC.

a Johnson & Johnson company

Instructions, Instrucciones, Gebrauchsanweisung, Istruzioni, Instruccões, Instrucciones,
Gebrauksaanwijzing, Brugsvejledning, Ohje, Οδηγίες, Bruksanvisning, Instrukcja,
Utasítások, Navod k použití, Navod, 説明書

57 40



2

4.1

58

English

Indications

The LIGACLIP ERCA Endoscopic Rotating Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated. The tissue being ligated should be consistent with the size of the clip.

Contraindications

- DO NOT use the instrument for contraceptive tubal occlusion.
- DO NOT use the instrument on tissue structures or vessels upon which metal ligating clips would not normally be used.

Device Description

The LIGACLIP ERCA Endoscopic Rotating Multiple Clip Applier is a sterile, single patient use instrument designed to provide a means of ligation through ENDOPATH® Surgical Trocars. The instrument delivers 20 titanium clips that individually advance after each firing. The shaft is made of a low glare material that minimizes reflective distortion. It is designed to rotate 360° in either direction. The rotating knob is located to allow for a one-handed technique.

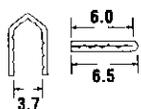
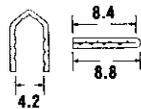
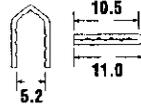
Product Code	Clip Size/ No. of Clips	Trocar Size	Clip Dimensions (mm)	Overall Shaft Length (approx.)
ER220	Medium/20	10/11 mm		28.5 cm
ER320	Medium-Large/20	10/11 mm		28.9 cm
ER420	Large/20	12 mm		34.1 cm

Illustration and Nomenclature (Illustration 1)

- | | |
|--------------------|------------------|
| 1. Low Glare Shaft | 4. Trigger |
| 2. Rotating Knob | 5. Applier Jaws |
| 3. Handle | 6. Indicator Bar |

Instructions for Use

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

- Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
- Fully squeeze the trigger** and then release to load the first clip into the instrument jaws. Failure to completely squeeze the trigger can result in clip misloading. (Illustration 2)
Note: The applier may be introduced through the appropriate diameter trocar sleeve with or without a clip in the jaw. The ratchet mechanism in the handle facilitates a one-way firing stroke and provides clip security in the jaws.
- Position the jaws with the clip completely around the vessel to be ligated. (Illustration 3)
- Fully squeeze the trigger** on each firing. Do so by pulling back on the trigger even after a sharp "click" is heard and until you touch plastic trigger to plastic handle (plastic to plastic).

59 4

- 5 Fully release the trigger after firing. A second "click" should be heard indicating the instrument is ready for the next firing. The next clip is automatically advanced as the trigger is released.
- 6 Inspect the instrument jaw tips after each use to ensure a new clip is present before the next firing.
Caution: Check to ensure that each clip has been securely placed around the tissue being ligated.
Note: When only three clips remain in the applier, a yellow clip counter indicating bar appears in the window.

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, 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 labeled to be immersed.
- Ensure that the clip is the correct size for the vessel or tubular structure being ligated.
- Prior to each clip application, inspect the jaw tips to ensure the clip is fully advanced to the end of the jaws.
- Ensure that each clip is securely and completely positioned around the tissue being ligated.
- The instrument should be **fully squeezed** on each firing.
- If a clip is dislodged prematurely from the jaw tip or fails to advance, remove the instrument from the patient. Completely squeeze the trigger to refire the instrument and then continue product use after successful firing.
- **Do not** excessively twist or torque the instrument jaws when positioning the instrument on a vessel and firing. Excessive twisting or torquing may result in clip malformation.
- **Do not** place excessive force on the proximal end of the instrument jaws when firing (pulling the trigger or releasing the trigger). Placing excessive force on the proximal end of the instrument jaws when firing may result in clip malformation.
- Ensure full release of the trigger after firing. A partial release of the trigger restricts the clip from reaching the correct distal point in the instrument jaws, and may result in clip malformation.
- **Never** fire the instrument over another clip or instrument. Firing the instrument in this manner may distort or yield the instrument jaws, which can cause the instrument to "spit" clips.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- Dispose of all opened products 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 LIGACLIP ERCA Endoscopic Rotating Multiple Clip Applier is supplied sterile and preloaded for single patient use. Discard after use.

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Ethicon Endo-Surgery, Inc.
510(k) Premarket Notification for Curved Cutter Stapler and Reloads

Section H

Material Biocompatibility

The biocompatibility of materials used in the LIGACLIP[®] 5M/L Endoscopic Multiple Clip Applier, Product Code EL5ML, 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 LIGACLIP[®] 5M/L Endoscopic Multiple Clip Applier 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.

All materials in the LIGACLIP[®] 5M/L Endoscopic Multiple Clip Applier are identical to those used in currently marketed medical devices.

The table in the following page lists the patient tissue contacting materials used in the LIGACLIP[®] 5M/L Endoscopic Multiple Clip Applier as well as those of the marketed device.

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Ethicon Endo-Surgery, Inc.
510(k) Premarket Notification for Curved Cutter Stapler and Reloads

Section J

Indications for Use Statement

The Indication for Use Statement for the proposed device is provided in the following page.

K05XXXX_EL5ML

February 10, 2005

7154

Indications for Use

510(k) Number (if known): _____

Device Name: LIGACLIP® 5 M/L 5 mm Endoscopic Multiple Clip Applier

Indications for Use:

The LIGACLIP® 5 M/L 5 mm Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated. The tissue being ligated should be consistent with the size of the clip.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

72 55

Indications for Use

510(k) Number (if known): _____

Device Name: LIGACLIP® 5 M/L 5 mm Endoscopic Multiple Clip Applier

Indications for Use:

The LIGACLIP® 5 M/L 5 mm Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated. The tissue being ligated should be consistent with the size of the clip.

Superseded

Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

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Ethicon Endo-Surgery, Inc.
510(k) Premarket Notification for LIGACLIP™ S M/L.

Section K

Truthful and Accurate Statement

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

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

Kimberly Shoemaker
Kimberly Shoemaker
Manager, Regulatory Affairs

2/10/05
Date

74 56

Ethicon Endo-Surgery, Inc.
510(k) Premarket Notification for LIGACLIP[®] 5 M/L

Section L

LIGACLIP[®] 5 M/L 510(k) Summary of Safety and Effectiveness

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Ethicon Endo-Surgery, Inc.
510(k) Premarket Notification for LIGACLIP[®] 5 M/L

LIGACLIP[®] 5 M/L 510(k) Summary of Safety and Effectiveness

Company

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

Contact

Kimberly Shoemaker
Manager, Regulatory Affairs

Date Prepared:

February 10, 2005

Name of Device

Trade Name: LIGACLIP[®] 5M/L Endoscopic Multiple Clip Applier
Classification Name: Implantable Clip

Predicate Devices:

Trade Name: LIGACLIP[®] ERCA Endoscopic Rotating Multiple Clip Applier
Cleared under 510(k) numbers K0864102 on November 5, 1986. The Titanium Clips used with the applier were cleared March 9, 1983 under K830503.

Device Description

The LIGACLIP[®] 5 M/L Endoscopic Multiple Clip Applier is a sterile, single patient use, disposable surgical instrument designed to provide a means of ligation through an appropriately sized trocar. The instrument configuration consists of a pistol grip handle, an actuation trigger, a rotation knob, a shaft having an outer diameter of 5.5mm and a length of 33cm. At the distal end of the shaft is a set of jaws for forming ligating clips. The device contains 15 clips.

Indications for Use

The LIGACLIP[®] 5 M/L 5 mm Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated. The tissue being ligated should be consistent with the size of the clip.

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Ethicon Endo-Surgery, Inc.
510(k) Premarket Notification for LIGACLIP[®] 5 M/L.

Technological Characteristics

The LIGACLIP[®] 5 M/L 5 mm Endoscopic Multiple Clip Applier is identical to the predicate device with respect to intended use. The device is operated in a manner similar to the predicate device.

Performance Data

Bench testing was performed to ensure that the device performs as intended. All testing results demonstrated satisfactory performance.

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Ethicon Endo-Surgery, Inc.
510(k) Premarket Notification for LIGACLIP® 5 M/L

LIGACLIP® 5 M/L 510(k) Summary of Safety and Effectiveness

Company

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

Contact

Kimberly Shoemaker
Manager, Regulatory Affairs

Date Prepared:

February 10, 2005

Name of Device

Trade Name: LIGACLIP® 5M/L Endoscopic Multiple Clip Applier
Classification Name: Implantable Clip

Predicate Devices:

Trade Name: LIGACLIP® ERCA Endoscopic Rotating Multiple Clip Applier
Cleared under 510(k) numbers K0864102 on November 5, 1986. The Titanium Clips used with the applier were cleared March 9, 1983 under K830503.

Device Description

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Indications for Use

The LIGACLIP® 5 M/L 5 mm Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated. The tissue being ligated should be consistent with the size of the clip.

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Ethicon Endo-Surgery, Inc.
510(k) Premarket Notification for LIGACLIP® 5 M/L

Technological Characteristics

The LIGACLIP® 5 M/L 5 mm Endoscopic Multiple Clip Applier is identical to the predicate device with respect to intended use. The device is operated in a manner similar to the predicate device.

Performance Data

Bench testing was performed to ensure that the device performs as intended. All testing results demonstrated satisfactory performance.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

March 9, 2005

From: Reviewer(s) - Name(s) David Krause, PhD

Subject: 510(k) Number 2050344

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

NA

The indication for use form

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

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):

Implantable clip, Class II
F2P, 878, 4300

Review: Steph Plueds PRSB 3/10/05
(Branch Chief) (Branch Code) (Date)

Final Review: Mark J. Miller 3/11/05
(Division Director) (Date)

Revised: 4/2/03

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	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 #191-2 and Federal Register 90N0332, September 10, 1991.	N/A	A

6

**"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION
K050344**

Reviewer: David Krause, PhD, Expert Biologist

Division/Branch: DGRND/PRSB

Device Name: LIGACLIP® 5 M/L 5 mm Endoscopic Multiple Clip Applier

Product To Which Compared [510(K) Number If Known]: Same (K864102 & K830503)

YES NO

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

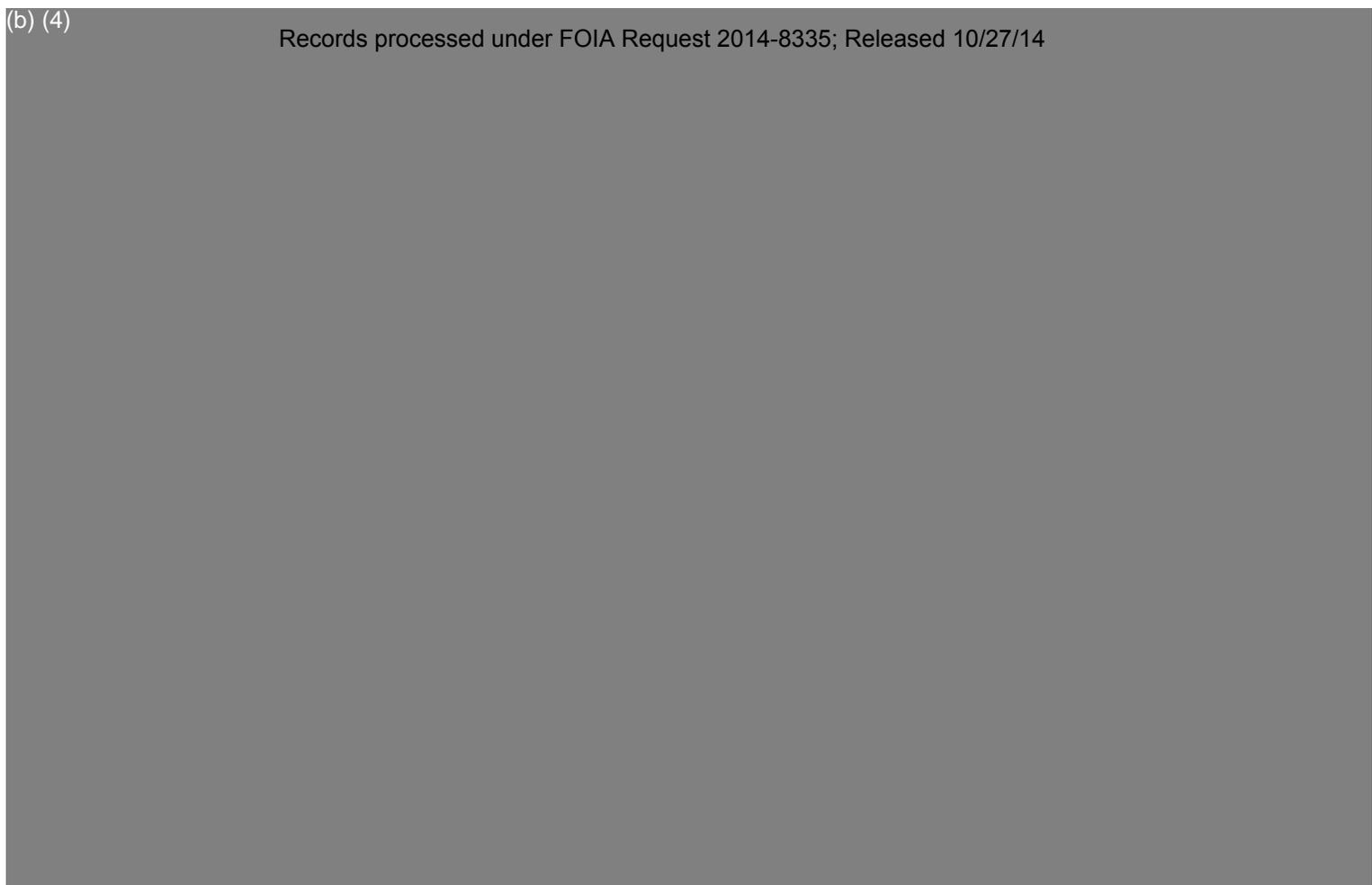
Intended Use: The LIGACLIP® 5 M/L 5 mm Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated.

Device Description: The LIGACLIP® 5 M/L Endoscopic Multiple Clip Applier is a sterile, single patient use, disposable surgical instrument designed to provide ligation through a trocar. The instrument has a pistol grip handle, an actuation trigger, a rotation knob, a shaft having an outer diameter of 5.5 mm and a length of 33 cm. The distal end of the shaft includes a set of jaws for forming ligating clips. The device includes 15 medium sized ASTM Grade 1 titanium clips with a Yield Strength of approximately 55 kpsi that have an unformed aperture of 3.6 mm, a formed length of 8.8 mm, are 0.75 mm wide and 0.50 mm thick. The final formed clip is achieved by actuation of the jaws via the trigger.

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:**
- 5. Describe the new technological characteristics:**
- 6. Explain how new characteristics could or could not affect safety or effectiveness:**
- 7. Explain how descriptive characteristics are not precise enough:**
- 8. Explain new types of safety or effectiveness questions raised or why the questions are not new:**
- 9. Explain why existing scientific methods can not be used:**
- 10. Explain what performance data is needed:**
- 11. Explain how the performance data demonstrate that the device is or is not substantially equivalent:**

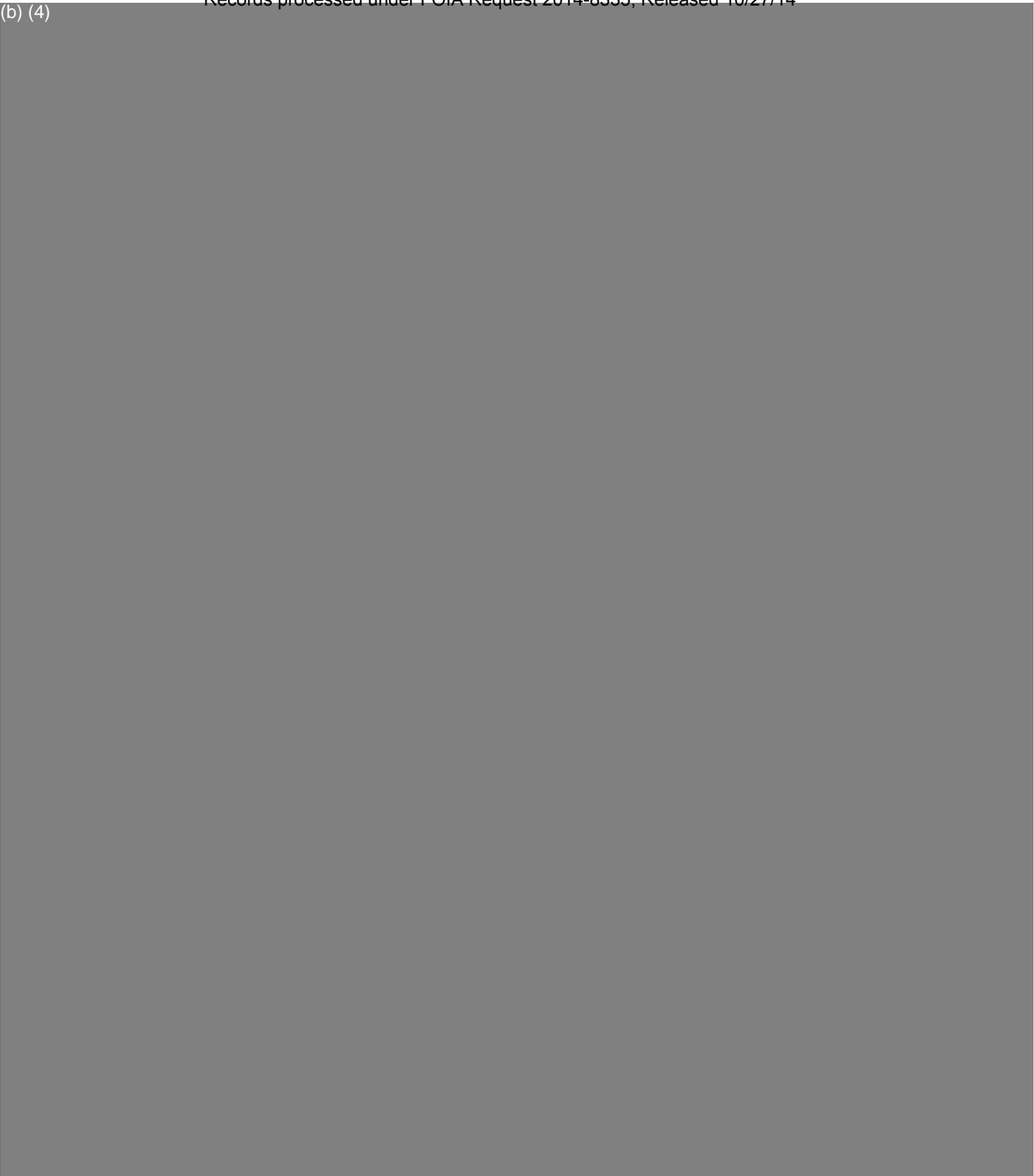
For further details please see Review Memo.



3/9/2005

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(b) (4)



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ETHICON ENDO-SURGERY, INC
a Johnson & Johnson company
4545 CREEK ROAD
CINCINNATI, OHIO 45242-2839

Indications for Use

510(k) Number (if known): _____

Device Name: LIGACLIP® 5 M/L 5 mm Endoscopic Multiple Clip Applier

Indications for Use:

The LIGACLIP® 5 M/L 5 mm Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use

(21 CFR 801 Subpart C)

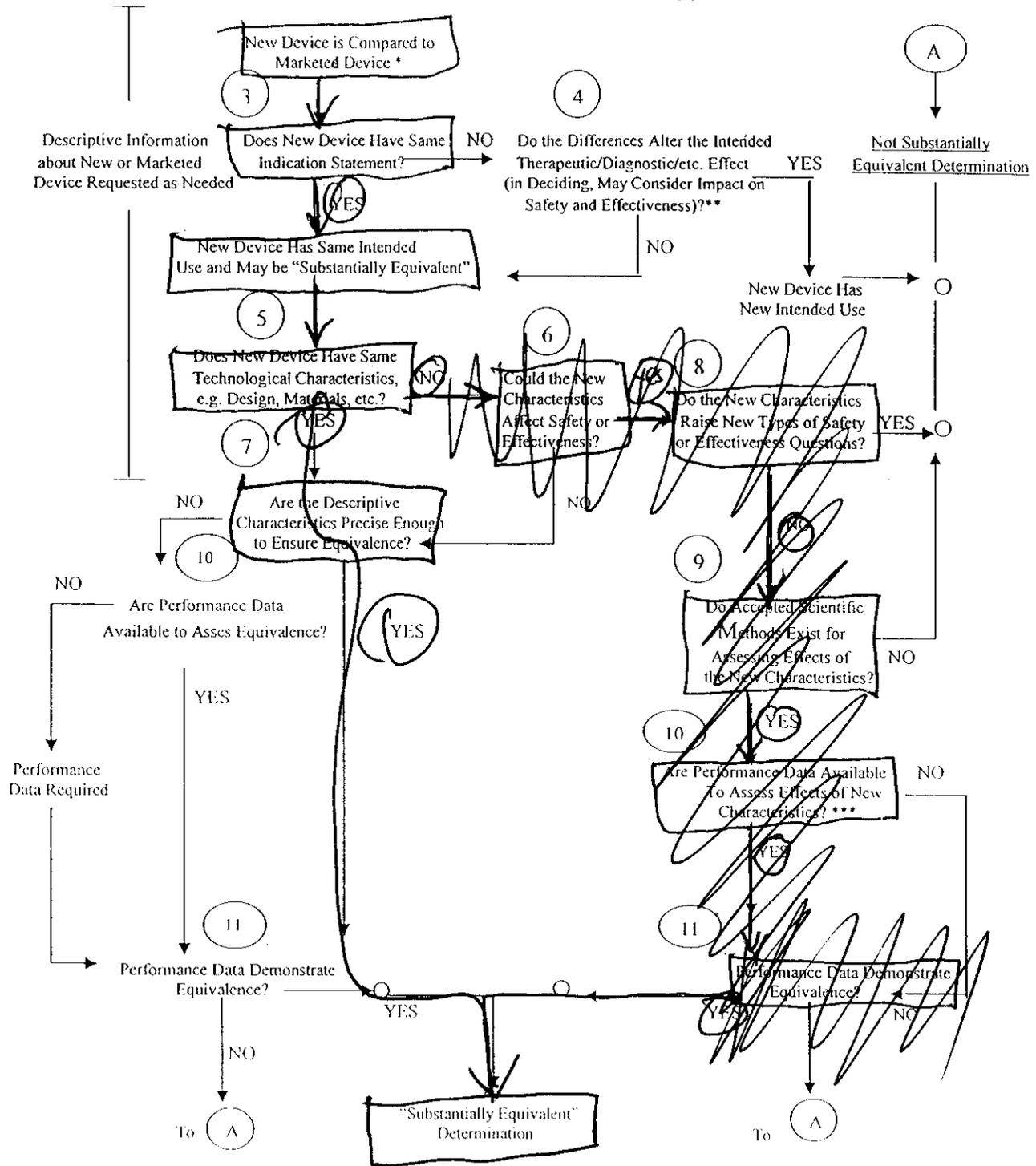
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

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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.