

K110699

Ethicon Endo-Surgery, LLC

510(k) Premarket Notification (Traditional) for Ligamax 5

MAR 25 2011

510(k) Summary

Company

Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, PR 00969

Contact

Emily Kruezkamp, Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc
Telephone: (513) 337-1546
Fax: (513) 337-2802
Email: ekruezk@its.jnj.com

Date Prepared: March 9, 2011

Device Name

Trade Name: Ligamax™ 5
Common Name: Clip Applier

Classification Names

Implantable Clip

Predicate Device

Ligamax™ 5, a 5 MM Endoscopic Multiple Clip Applier, cleared under K050344 on March 14, 2005 as Ligaclip 5 M/L

Device Description:

The Ethicon Endo-Surgery Ligamax 5 is a 5 mm endoscopic multiple clip applier. This sterile, single patient use, instrument is designed to provide a means of ligation on tubular structures or vessels through an appropriately-sized trocar. The instrument contains 15 medium-large titanium clips for occluding tissue, structures, and vessels.

Indication for Use:

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

Technological Characteristics:

The instrument configuration consists of a pistol handle portion, an actuation trigger, a rotation knob, and a shaft with an outer diameter of 5.5 mm and length of 33 cm. The shaft contains an etched line of demarcation, which aids the user's visualization when the device is adequately inserted through the trocar. At the distal end of the shaft are the jaws, which form ligating clips. The force to squeeze the trigger increases when there are no clips remaining in the device, this is known as the tactile last-clip lockout indicator.

Performance Data: Bench testing was performed to demonstrate that the device will perform as intended.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, LLC
% Ethicon Endo-Surgery, Inc.
Ms. Emily Kruetzkamp
Regulatory Affairs Associate
4545 Creek Road
Cincinnati, Ohio 45242

MAR 25 2011

Re: K110699
Trade/Device Name: Ligamax™ 5
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW, GAG
Dated: March 10, 2011
Received: March 14, 2011

Dear Ms. Kruetzkamp:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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

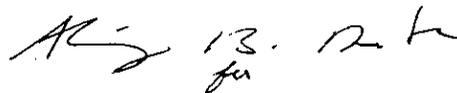
Page 2 - Ms. Emily Kruetzkamp

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson" with a stylized flourish at the end.

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

Enclosure

Ethicon Endo-Surgery, LLC

510(k) Premarket Notification (Traditional) for Ligamax 5

Indications for Use Form

Indications for Use

510(k) Number (if known): K110699

Device Name: Ligamax™ 5

Indications for Use:

The 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)

(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

David Krone

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110699



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, LLC
% Ethicon Endo-Surgery, Inc.
Ms. Emily Kruetzkamp,
Regulatory Affairs Associate
4545 Creek Road
Cincinnati, Ohio 45242

MAR 25 2011

Re: K110699
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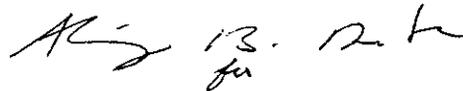
Page 2 - Ms. Emily Kruetzkamp

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Sincerely yours,



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

Enclosure

Ethicon Endo-Surgery, LLC

510(k) Premarket Notification (Traditional) for Ligamax 5

Indications for Use Form

Indications for Use

510(k) Number (if known): K110699

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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(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

Daniel Krone

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110699



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Control Center WO66-G609
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

March 15, 2011

ETHICON ENDO-SUGERY, LLC
 C/O ETHICON ENDO-SURGERY, INC.
 4545 CREEK RD.
 CINCINNATI, OHIO 45242
 ATTN: EMILY KRUEZKAMP

510k Number: K110699

Received: 3/14/2011

Product: LIGAMAX 5

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

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

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff



K110699

4545 CREEK ROAD
CINCINNATI, OH 45242-2414

MAR 14 2011

March 10, 2011

Received

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of General and Plastic Surgery Devices
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Traditional 510(k) Premarket Notification, Ligamax™ 5

Dear Sir or Madam:

Pursuant to 21 CFR 807.90, Ethicon Endo-Surgery is submitting two copies of this 510(k) notification for the Ethicon Endo-Surgery Ligamax™ 5. The design of the device is based upon the predicate device Ligamax 5, submitted as LIGACLIP 5 M/L, cleared under K050344 on March 14, 2005. The basis of this submission is a modification of a legally marketed device that would not otherwise qualify for a Special 510(k).

The following information is provided in this cover letter per the guidance document *Format for Traditional and Abbreviated 510(k)s*:

Submission Type:	Traditional 510(k)
Submission Date:	March 10, 2011
510(k) Submitter:	Ethicon Endo-Surgery, LLC
Contact Information:	Emily Kruetzkamp, Regulatory Affairs Associate Phone: 513.337.1546 Fax: 513.337.2802 Email: ekruetzka@its.jnj.com
Common Name:	Clip Applier
Trade Name:	Ligamax 5
Classification Name:	Clip, Implantable
Device Class:	Class II
Panel:	General & Plastic Surgery
Classification Codes:	FZP
Classification Regulations:	878.4300
Predicate:	Ligamax 5, submitted as LIGACLIP 5 M/L, K050344
Establishment Registration:	3005075853

The basis of this 510(k) is device modifications to device subcomponents in addition to incremental changes to the device since the last 510(k) submission. Each individual change has not necessitated a premarket notification filing. This decision is based upon an assessment of information with regard to the changes and a review of the device with respect to the regulatory baseline.

Confidentiality Preference: Please keep this submission confidential per 21 CFR 807.95

The following table contains answers to general questions regarding this submission.

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

The unique payment identification number (PIN) assigned to this submission is MD6054146-956733. A copy of the Medical Device User Fee Cover Sheet, included in Section 1, is provided for reference.

Per the instructions accessed at 'Electronic Copies for Pre-Market Submissions', an electronic copy is provided with this submission and it is an exact duplicate of the original paper submission. The electronic copy is accompanied by extra copies of the 510(k) cover letter and the 510(k) truthful and accuracy statement with original signatures.

All information necessary for a substantial equivalence determination is included herein. If there are any questions concerning this notification, please contact me at 513.337.1546 or by email at ekruetzka@its.jnj.com. If I am not available, the alternate contact person for this submission is Kimberly Shoemaker, Group Manager Regulatory Affairs, at 513.337.8123 or by email at kshoema1@its.jnj.com.

Sincerely,



Emily Kruezkamp

Regulatory Affairs Associate

Table of Contents

Table of Contents	1
Section 1: Medical Device User Fee Cover Sheet (Form FDA 3601).....	2
Section 2: CDRH Premarket Review Submission Cover Sheet	4
Section 3: 510(k) Cover Letter	10
Section 4: Indications for Use Statement.....	13
Section 5: 510(k) Summary	15
Section 6: Truthful and Accuracy Statement.....	17
Section 7: Class III Summary and Certification	19
Section 8: Financial Certification or Disclosure Statement.....	20
Section 9: Declarations of Conformity and Summary Reports	21
Section 10: Executive Summary.....	22
Section 11: Device Description	26
Section 12: Substantial Equivalence Discussion	35
Section 13: Proposed Labeling	44
Section 14: Sterilization and Shelf Life.....	61
Section 15: Biocompatibility	62
Section 16: Software.....	63
Section 17: Electromagnetic Compatibility and Electrical Safety.....	64
Section 18: Performance Testing – Bench.....	65
Section 19: Performance Testing – Animal.....	86
Section 20: Performance Testing – Clinical	87
Section 21: Other	88
Section 22: FDA Form 3674.....	109

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

The Medical Device Use Fee Cover Sheet for this device is provided on the following page.

Ethicon Endo-Surgery, LLC

510(k) Premarket Notification (Traditional) for Ligamax 5

Form Approved: OMB No. 0910-511. 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. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) ETHICON ENDO SURGERY INC 4545 CREEK RD CINCINNATI OH 45242 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****7572		2. CONTACT NAME Emily Kruezkamp 2.1 E-MAIL ADDRESS ekruetzka@its.jnj.com 2.2 TELEPHONE NUMBER (include Area code) 513-3371546 2.3 FACSIMILE (FAX) NUMBER 513 337 2802	
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:			
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.			
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
7. 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)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)			

07-Feb-2011

Form FDA 3601 (01/2007)

CONFIDENTIAL

pg. 3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section 2: CDRH Premarket Review Submission Cover Sheet

The CDRH Premarket Review Submission Cover Sheet for this device is provided on the following page.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET	Form Approval OMB No. 0910-0120 Expiration Date: December 31, 2013 See OMB Statement on page 5.
---	--

Date of Submission February 28 2011	User Fee Payment ID Number (b) (4)	FDA Submission Document Number (if known)
--	---------------------------------------	---

SECTION A TYPE OF SUBMISSION				
PMA <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	PMA & HDE Supplement <input type="checkbox"/> Regular (180 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	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <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	Meeting <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):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <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, LLC	Establishment Registration Number (if known) 3005075853		
Division Name (if applicable) N/A	Phone Number (including area code) (b) (4)		
Street Address 475 Calle C	FAX Number (including area code) (b) (4)		
City Guaynabo	State / Province Puerto Rico	ZIP/Postal Code 00969	Country USA
Contact Name (b) (4)			
Contact Title Director, GLC Quality		Contact E-mail Address lriver22@its.jnj.com	

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

Company / Institution Name Ethicon Endo-Surgery, Inc	Phone Number (including area code) (513) 337 1546		
Division Name (if applicable) N/A	FAX Number (including area code) (513) 337 2729		
Street Address 4545 Creek Road	State / Province OH	ZIP Code 45242	Country USA
City Cincinnati			
Contact Name Emily Kruezkamp			
Contact Title Regulatory Affairs Associate		Contact E-mail Address ekruezk@its.jnj.com	

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> New Device <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 (<i>specify below</i>)	<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"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (<i>specify below</i>)	<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 (<i>specify below</i>)	<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 (<i>specify</i>):					

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"/> 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"/> 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 <input type="checkbox"/> Request Hearing			
<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"/> Other Reason (<i>specify</i>):					

SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			

<input checked="" type="checkbox"/> Other Reason (<i>specify</i>): A 510(k) is required due to the aggregation of minor changes since the last 510(k), even though specific recent changes may not necessitate a filing. This decision is based upon the information provided with regard to the change and a review of the device against the regulatory baseline.		
--	--	--

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 information			
1	EL5ML	2		3		4		<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	K050344	LIGAMAX 5	Ethicon Endo-Surgery, LLC
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name
 Clip applier

	Trade or Proprietary or Model Name for This Device	Model Number
1	LIGAMAX 5	1 EL5ML
2		
3		
4		
5		

FDA document numbers of all prior related submissions (regardless of outcome)					
1		3		5	
7		9		11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code FZP	C.F.R. Section (if applicable) 878.4300	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Clip, Implantable		

Indications (from labeling)
 The 5 mm Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated.

<p>Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.</p>		<p>FDA Document Number (if known)</p>	
<p>SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION</p>			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	<p>Facility Establishment Identifier (FEI) Number</p> <p>3005075853</p>	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
<p>Company / Institution Name</p> <p>Ethicon Endo-Surgery, LLC</p>		<p>Establishment Registration Number</p> <p>3005075853</p>	
<p>Division Name (if applicable)</p> <p>N/A</p>		<p>Phone Number (including area code)</p> <p>(b) (4)</p>	
<p>Street Address</p> <p>475 Calle C</p>		<p>FAX Number (including area code)</p> <p>(b) (4)</p>	
<p>City</p> <p>Guaynabo</p>	<p>State / Province</p> <p>Puerto Rico</p>	<p>ZIP Code</p> <p>00969</p>	<p>Country</p> <p>USA</p>
<p>Contact Name</p> <p>(b) (4)</p>	<p>Contact Title</p> <p>Director, GLC Quality</p>	<p>Contact E-mail Address</p> <p>(b) (4)</p>	
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	<p>Facility Establishment Identifier (FEI) Number</p> <p>1628808</p>	<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Manufacturer	<input checked="" type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
<p>Company / Institution Name</p> <p>Ethicon Endo-Surgery, Inc.</p>		<p>Establishment Registration Number</p> <p>1628808</p>	
<p>Division Name (if applicable)</p> <p>N/A</p>		<p>Phone Number (including area code)</p> <p>(b) (4)</p>	
<p>Street Address</p> <p>3801 University Blvd, S.E.</p>		<p>FAX Number (including area code)</p> <p>(b) (4)</p>	
<p>City</p> <p>Albuquerque</p>	<p>State / Province</p> <p>NM</p>	<p>ZIP Code</p> <p>87106</p>	<p>Country</p> <p>USA</p>
<p>Contact Name</p> <p>R (b) (4)</p>	<p>Contact Title</p> <p>Manager, Plant Quality Systems</p>	<p>Contact E-mail Address</p> <p>(b) (4)</p>	
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	<p>Facility Establishment Identifier (FEI) Number</p> <p>9710649</p>	<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
<p>Company / Institution Name</p> <p>Ethicon Endo-Surgery, Inc., S.A. de CV Planta II</p>		<p>Establishment Registration Number</p> <p>9710649</p>	
<p>Division Name (if applicable)</p> <p>N/A</p>		<p>Phone Number (including area code)</p> <p>(b) (4)</p>	
<p>Street Address</p> <p>Calle Durango No. 2751, Colonia Lote Bravo</p>		<p>FAX Number (including area code)</p> <p>(b) (4)</p>	
<p>City</p> <p>Ciudad Juarez</p>	<p>State / Province</p> <p>Chihuahua</p>	<p>ZIP Code</p>	<p>Country</p> <p>Mexico</p>
<p>Contact Name</p> <p>(b) (4)</p>	<p>Contact Title</p> <p>QA Manager</p>	<p>Contact E-mail Address</p> <p>(b) (4)</p>	

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	(b) (4)				
2	(b) (4)				
3	(b) (4)				
4	(b) (4)				
5					
6					
7					

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

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

Department of Health and Human Services
 Food and Drug Administration
 Office of Chief Information Officer
 1350 Piccard Drive, Room 400
 Rockville, MD 20850

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

Section 3: 510(k) Cover Letter

The signed cover letter for this submission is provided on the following pages.



4545 CREEK ROAD
CINCINNATI, OH 45242-2839

March 10, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of General and Plastic Surgery Devices
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Traditional 510(k) Premarket Notification, Ligamax™ 5

Dear Sir or Madam:

Pursuant to 21 CFR 807.90, Ethicon Endo-Surgery is submitting two copies of this 510(k) notification for the Ethicon Endo-Surgery Ligamax™ 5. The design of the device is based upon the predicate device Ligamax 5, submitted as LIGACLIP 5 M/L, cleared under K050344 on March 14, 2005. The basis of this submission is a modification of a legally marketed device that would not otherwise qualify for a Special 510(k).

The following information is provided in this cover letter per the guidance document *Format for Traditional and Abbreviated 510(k)s*:

Submission Type: Traditional 510(k)
Submission Date: March 10, 2011
510(k) Submitter: Ethicon Endo-Surgery, LLC
Contact Information: Emily Kruetzkamp, Regulatory Affairs Associate
Phone: 513.337.1546
Fax: 513.337.2802
Email: ekruetzk@its.jnj.com

Common Name: Clip Applier
Trade Name: Ligamax 5
Classification Name: Clip, Implantable
Device Class: Class II
Panel: General & Plastic Surgery
Classification Codes: FZP
Classification Regulations: 878.4300
Predicate: Ligamax 5, submitted as LIGACLIP 5 M/L, K050344
Establishment Registration: 3005075853

The basis of this 510(k) is device modifications to device subcomponents in addition to incremental changes to the device since the last 510(k) submission. Each individual change has not necessitated a premarket notification filing. This decision is based upon an assessment of information with regard to the changes and a review of the device with respect to the regulatory baseline.

Confidentiality Preference: Please keep this submission confidential per 21 CFR 807.95

The following table contains answers to general questions regarding this submission.

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

The unique payment identification number (PIN) assigned to this submission is MD6054146-956733. A copy of the Medical Device User Fee Cover Sheet, included in Section 1, is provided for reference.

Per the instructions accessed at 'Electronic Copies for Pre-Market Submissions', an electronic copy is provided with this submission and it is an exact duplicate of the original paper submission. The electronic copy is accompanied by extra copies of the 510(k) cover letter and the 510(k) truthful and accuracy statement with original signatures.

All information necessary for a substantial equivalence determination is included herein. If there are any questions concerning this notification, please contact me at 513.337.1546 or by email at ekruetzka@its.jnj.com. If I am not available, the alternate contact person for this submission is Kimberly Shoemaker, Group Manager Regulatory Affairs, at 513.337.8123 or by email at kshoema1@its.jnj.com.

Sincerely,



Emily Kruetzka

Regulatory Affairs Associate

Section 4: Indications for Use Statement

The Indication for Use statement for the proposed device is provided on the following page.

Ethicon Endo-Surgery, LLC

510(k) Premarket Notification (Traditional) for Ligamax 5

Indications for Use Form

Indications for Use

510(k) Number (if known): _____

Device Name: Ligamax™ 5_____

Indications for Use:

The 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 AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Section 5: 510(k) Summary

The 510(k) Summary for the subject device is on the following pages.

510(k) Summary

Company

Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, PR 00969

Contact

Emily Kruetzkamp, Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc
Telephone: (513) 337-1546
Fax: (513) 337-2802
Email: ekruetzk@its.jnj.com

Date Prepared: March 9, 2011

Device Name

Trade Name: Ligamax™ 5
Common Name: Clip Applier

Classification Names

Implantable Clip

Predicate Device

Ligamax™ 5, a 5 MM Endoscopic Multiple Clip Applier, cleared under K050344 on March 14, 2005 as Ligaclip 5 M/L

Device Description:

The Ethicon Endo-Surgery Ligamax 5 is a 5 mm endoscopic multiple clip applier. This sterile, single patient use, instrument is designed to provide a means of ligation on tubular structures or vessels through an appropriately-sized trocar. The instrument contains 15 medium-large titanium clips for occluding tissue, structures, and vessels.

Indication for Use:

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

Technological Characteristics:

The instrument configuration consists of a pistol handle portion, an actuation trigger, a rotation knob, and a shaft with an outer diameter of 5.5 mm and length of 33 cm. The shaft contains an etched line of demarcation, which aids the user's visualization when the device is adequately inserted through the trocar. At the distal end of the shaft are the jaws, which form ligating clips. The force to squeeze the trigger increases when there are no clips remaining in the device, this is known as the tactile last-clip lockout indicator.

Performance Data: Bench testing was performed to demonstrate that the device will perform as intended.

Section 6: Truthful and Accuracy Statement

The Truthful and Accuracy Statement for the device is provided on the following page.

Ethicon Endo-Surgery, LLC

510(k) Premarket Notification (Traditional) for Ligamax 5

Truthful and Accuracy Statement

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

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



Emily Krutzkamp
Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc



Date

Section 7: Class III Summary and Certification

This section does not apply; the Ligamax 5 is a Class II device.

Section 8: Financial Certification or Disclosure Statement

This section does not apply; no clinical study was performed to support this submission.

Section 9: Declarations of Conformity and Summary Reports

This section does not apply; this submission is a Traditional 510(k).

Section 10: Executive Summary

The purpose of this 510(k) is to notify FDA of design changes and incremental enhancements made to the Ethicon Endo-Surgery Ligamax™ 5 Endoscopic Multiple Clip Applier. Since the regulatory baseline submission of Ligamax 5, K050344, several modifications have been made to enhance design and manufacturing capability. Each change was evaluated in accordance with Ethicon Endo-Surgery's Quality Systems procedures and has not necessitated a filing of a new premarket notification.

The effect of the latest design change, considered together with all previous changes since the last 510(k) clearance, led to a decision to submit a new 510(k). Therefore, this 510(k) incorporates all changes and compares the device to the regulatory baseline device. Changes that triggered this 510(k) are distinguished from incremental changes and described in Section 11, Table 11.1 and Table 11.2.

Device Description

The Ethicon Endo-Surgery Ligamax 5 is a 5 mm endoscopic multiple clip applier. This sterile, single patient use, instrument is designed to provide a means of ligation on tubular structures or vessels through an appropriately-sized trocar. The instrument contains 15 medium-large titanium clips for occluding tissue, structures, and vessels.

The subject device has many of the same technological characteristics as the predicate device, such as the handle design with an actuation trigger, rotation knob, shaft with an outer diameter of 5.5 cm and a length of 33 cm, and an end effector portion with jaws for forming ligating clips. Additionally, the feed-form sequence, ligating clips, and indication for the subject device have not changed.

Design changes described in this submission include an increase in the jaw aperture; changed feed link return spring to accommodate the changes in the feeding system;

(b) (4)

(b) (4)

and updated component dimensions to enhance consistency of the visual clip count indicator. Incremental enhancements of the device, also illustrated in this submission, include an etched line to improve visualization when the instrument has been adequately inserted through the trocar; changed clip feeding components such as the advancer, feedbar, and tissue stop; modified components to increase force of the tactile last-clip lockout indicator; and (b) (4)

(b) (4)

The Ligamax 5 indications and contraindications are identical to the predicate. The indication is:

- The 5 mm Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated.

The contraindications are:

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

The following Table 10.1 provides a detailed side-by-side comparison of the subject device and the predicate device with respect to technology and device performance.

Table 10.1 Device Comparison Table: Technology, and Performance

Characteristic	Subject Device Description	Predicate Device, K050344
Similarities		
Basic Clip Geometry	Apex and knee geometry, also known as traditional barn shape	Identical
Clip Aperture	(b) (4)	Identical
Clip Closed Length	(b) (4)	Identical
Clip Crimp Pads	Crimp pads allow instrument jaws to concentrate force near the clip apex, and fully from the clip	Identical
Clip Cross Section	(b) (4)	Identical
Clip Material	(b) (4)	Identical
Clip Pattern	(b) (4)	Identical
Number of Preloaded Clips	15	Identical
Shaft Length	33 cm	Identical
Shaft Diameter	5.5 mm	Identical
Cholangio-click	Click signals that a clip has been partially formed to secure a Cholangiogram catheter	Identical
Clip Indicator	Indicator becomes progressively more visible when 3 or fewer clips remain in the device	Identical
Audible and tactile feedback	Ratchet or click sound during clip loading and the “cholangio click” portion of the firing sequence	Identical
Feed-Form Sequence (user interface)	The device is ready for use upon removal from the package. To feed a clip into the instrument jaws, the trigger is squeezed approximately one-third of the firing stroke. The fed clip in the jaws can now be placed over the targeted structure or vessel. To form the clip onto the targeted structure or vessel, the trigger is fully squeezed toward the instrument handle until it touches the handle.	Identical
Trocar Compatibility	Jaws collapse passively during insertion, but reopen after clearing the distal tip of the trocar cannula. This enables 5 mm trocar insertions.	Identical
Rotation Knob	Allows the shaft to move 360°	Identical
Overload Mechanism	Prevents excessive force applied to jaws if jaws are fired over an unintended structure, maintains jaw reliability	Identical
Handle and Trigger Ergonomics	Conventional pistol-grip configuration with actuation "firing" trigger	Identical

Ethicon Endo-Surgery, LLC

510(k) Premarket Notification (Traditional) for Ligamax 5

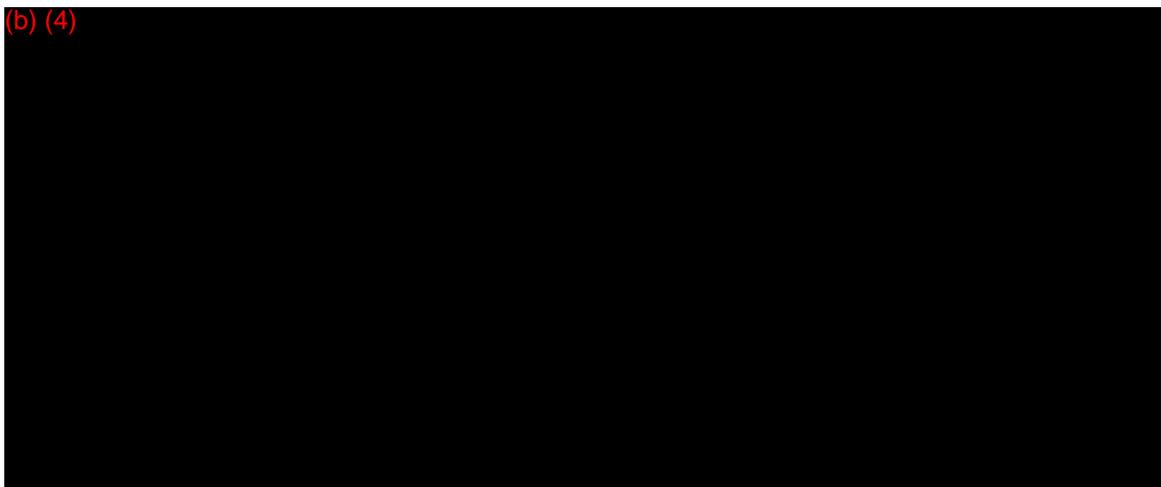
Characteristic	Subject Device Description	Predicate Device, K050344
Device Description	The 5 mm Endoscopic Multiple Clip Applier is a sterile, single patient use instrument designed to provide a means of ligation through an appropriately-sized trocar. The instrument contains 15 titanium clips and the shaft can be rotated 360° in either direction.	Identical
Shelf Life	5 years	Identical
Sterilization Process	[REDACTED] (b) (4)	Identical
Differences		
Jaw Aperture	(b) (4)	[REDACTED]
Line of Demarcation, on distal end of the shaft near the jaws	Etched Line	Line distinguished by 2 materials meeting in a line
Force to fire through the Tactile “No-clip Lockout” Indicator	(b) (4)	[REDACTED]

Summary of Performance Testing

The following bench performance testing was completed to demonstrate substantial equivalence of the subject device to the predicate device. Details concerning the test methods, acceptance criteria, results and discussion are contained in Section 18 Performance Testing - Bench.

Device performance was assessed against the design requirement for each of the following functions:

(b) (4)

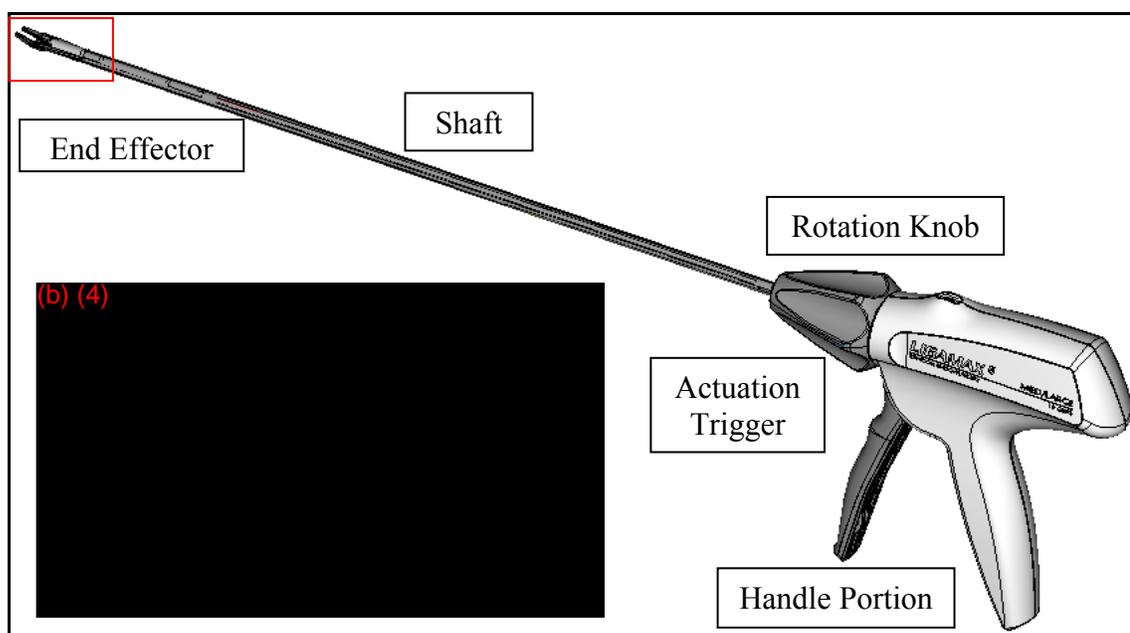


Section 11: Device Description

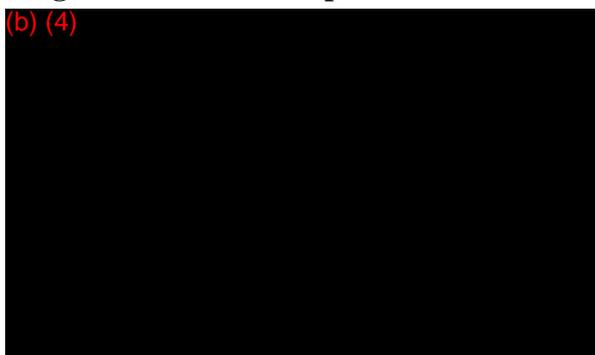
Device Design

The Ethicon Endo-Surgery Ligamax™ 5 is a 5 mm endoscopic multiple clip applicator. This sterile, single patient use, instrument is designed to provide a means of ligation on tubular structures or vessels through an appropriately-sized trocar. The instrument configuration interface consists of a pistol handle portion, an actuation trigger, a rotation knob, a shaft with an outer diameter of 5.5 mm and a length of 33 cm. The shaft contains an etched line of demarcation, which aids the user's visualization when the device is adequately inserted through the trocar. At the distal end of the shaft are the jaws, which form ligating clips. See Figure 11.1.

Figure 11.1 Device Parts



The instrument is preloaded with 15 medium-large titanium clips for occluding tissue, structures, and vessels. The clip design features an apex and knee geometry, also known as a traditional barn shape, with a tongue and groove formation on the inside corners of the clip, which is designed to reduce the gap in a formed clip. (b) (4)
 (b) (4) The clip design and materials are identical to the marketed device. See Figure 11.2.

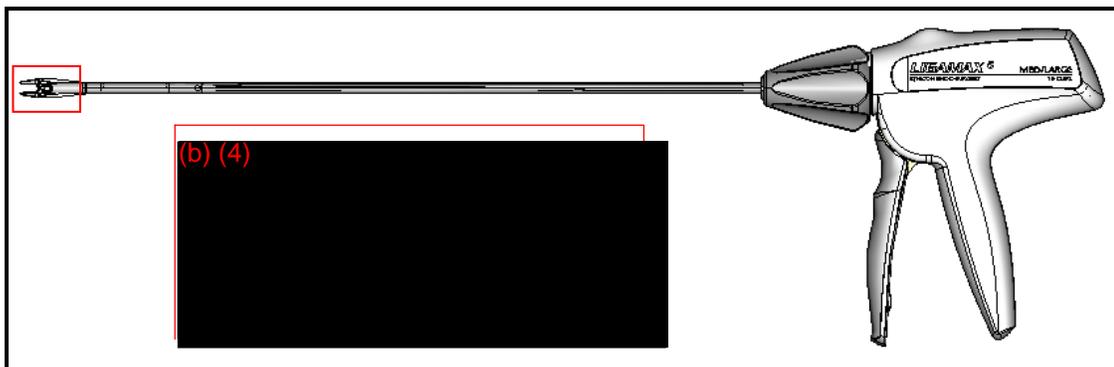
Figure 11.2 Device Clip**Principles of Operation**

The instrument, used for endoscopic surgical procedures, is inserted through an appropriately sized trocar cannula in order to access the surgical site. The instrument jaws are designed to passively close upon entering the trocar cannula and then fully reopen once the jaws are a sufficient distance beyond the distal end of the trocar cannula (see Figure 11.3). The jaws are designed with non-sharp edges and features to prevent inadvertent damage to tissue or tearing of trocar seals.

Figure 11.3 Demonstration of the Jaws Opening as it Passes through a Trocar

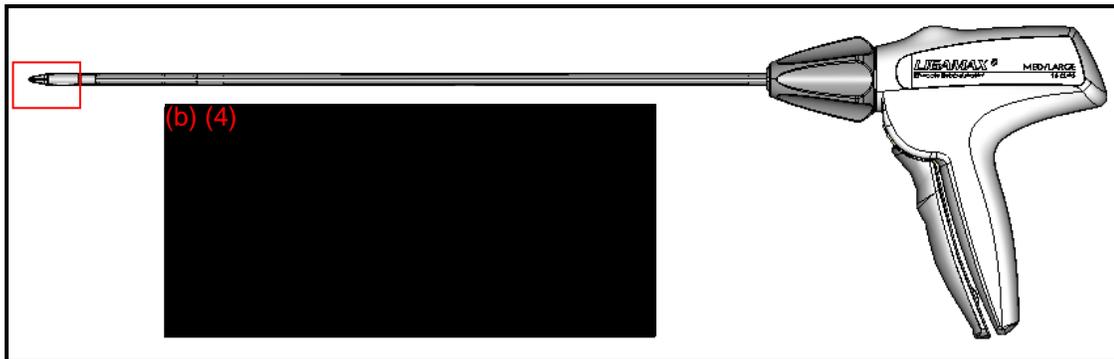
To feed a clip into the instrument jaws, the trigger is squeezed approximately one-third of the firing stroke (Figure 11.4). This initial trigger actuation not only feeds the most distal clip into the jaws, but also indexes the remaining clips inside the shaft to prepare them for the next cycle. The instrument is designed with a (b) (4) to hold the trigger position in place if the trigger is released. The fed clip in the jaws can now be placed over the targeted structure or vessel. To facilitate visualization and enable access to the targeted site, the shaft can be rotated 360° by means of the rotation knob.

Figure 11.4 Trigger Actuation



To form the clip on the targeted structure or vessel, the trigger is fully squeezed until it touches the handle. This final squeezing of the trigger causes the jaws to close (Figure 11.5), which in turn forms the clip.

Figure 11.5 Jaws Closed to Form Clip



During clip formation the distal tips of the clip move toward each other and touch, to form a diamond shape (Figure 11.6). This allows the targeted structure or vessel to be captured.

Figure 11.6 Clip Formation



The instrument is designed (b) (4) to hold the trigger position in place if the trigger is released prior to the designed ratchet disengagement point. The designed (b) (4) allows the clip to be partially formed over a Cholangiogram Catheter, if desired, and for the trigger to fully return to the full open position. The Cholangiogram clip form is shown in Figure 11.7.

Figure 11.7 Cholangiogram Clip



If the Cholangiogram clip form is not desired, the final forming of the clip flattens the diamond shape such that the legs of the formed clip become parallel to each other (see Figure 11.8). To ensure that this final clip form has been achieved the trigger is fully closed to the point that it touches the handle, as shown in Figure 11.5.

Figure 11.8 Final Clip Formation



Once a full clip formation has been completed, the release of the trigger automatically returns the trigger to the full open position. If the trigger is squeezed before it has fully returned to the full open position, (b) (4) provides resistance force to deter the closing trigger. The return of the trigger to the fully opened position allows the jaws to fully reopen and positions the next clip for the next firing.

The instrument is designed with two clip indicator features, which indicate to the user when the instrument has a limited number of clips remaining and when no clips are remaining. The first indication feature is a visual clip count indicator window located at the top of the handle. This clip indicator window provides a clip count indication for the last 3 clips in the instrument. The indication window is completely white during the first 12 clip firings. After the 13th clip firing, the indication window shows 1/3 orange. After the 14th clip firing, the indication window shows 2/3 orange. After the 15th clip firing, the indication window shows full orange. See Figure 11.9.

Figure 11.9 Clip Indicator

After 1-12 Firing	After 13 th Firing	After 14 th Firing	After 15 th Firing
(b) (4)			

The second indicator is the Tactile Indicator for “No-clip Lockout”. After all 15 clips have been fired and there are no clips remaining in the device, the force required to close the trigger increases. The magnitude of the increased force is designed to be high enough for the user to notice that the trigger actuation force without a clip is different than a normal trigger actuation force with a clip. The increased force requirement is designed to reduce the possibility that the empty jaws will be closed on a structure or vessel.

The instrument is also designed with an overload module that prevents excessive force from being applied to the instrument jaws if the jaws are closed over an unintended object such as another clip, Cholangiogram, or another surgical instrument. The overload module is located within the handle and includes a specific force limiter so that the forming stroke is diverted to the handle instead of the instrument jaws if an unintended object is within the jaws and the trigger is squeezed closed toward the handle.

Each of the above mentioned device features is found on both the subject and predicate device.

Incremental Design Changes

It was determined that a 510(k) is required prior to implementation of future design changes due to the aggregation of minor changes since the last 510(k). Per FDA Guidance Document “Deciding When to Submit a 510(k) for a Change to an Existing Device”:

“Because many changes occur in the evolution of a device, each change must be assessed individually, and collectively with other changes made since the last 510(k) clearance. When the effect of any one change, considered together with all previous changes since the last 510(k) clearance, leads a manufacturer to decide it is legally required to submit a new 510(k), then a 510(k) incorporating all the changes and comparing the new device to their legally-marketed device should be submitted. (The manufacturer should distinguish the change that triggers the 510(k) from those changes previously made for which a 510(k) was not required.)”

Since the regulatory baseline submission of the predicate Ligamax 5 (K050344) certain modifications have been made to enhance design and manufacturing capability. Each of these incremental changes were evaluated in accordance with relevant FDA Guidance, as well as Ethicon Endo-Surgery’s Quality Systems procedures, and at the time, were determined not to affect the safety and effectiveness, materials, or indications for use of Ligamax 5; therefore it was determined that these changes did not require submission of a 510(k). The Regulatory Determinations for these changes were documented with supporting data in the Regulatory files, which are linked to the Design History File.

Following a retrospective assessment, it was determined that this 510(k) submission is required because the sum of the incremental changes from the regulatory baseline. Cumulatively, these changes may be considered a modification in design. This submission identifies the design changes that triggered this 510(k) submission as well as incremental changes that, in isolation, did not necessitate a 510(k) submission. Design changes that triggered this 510(k) submission are listed in Table 11.1, and will not be released until this 510(k) is cleared. Incremental enhancements already implemented on

the marketed device are listed in Table 11.2. General device characteristics are listed in Section 10, Table 10.1 and Section 12, Table 12.3

Table 11.1 Design Changes that Triggered this 510(k) - implemented pending 510(k) clearance

Scope	Description	Reason for Change
Clip Indicator	Clip Indicator - Visual Clip Count Indicator	<p>The indicator wheel provides the white and orange indication color and is designed to rotate the indicator wheel after each clip feeding cycle. The clip count indicator includes the following adjustments of internal actuator components:</p> <ul style="list-style-type: none"> • (b) (4) • [REDACTED] <p>These changes enhance the correctness of the Visual Clip Count Indicator to meet updated design requirements.</p>
Clip Feeding and Forming	Spring Change, Retraction of the Feeding Systems	(b) (4)
Clip Feeding	Jaw Aperture	(b) (4)
Device Assembly Robustness	Closure Coupler Pin Hole	(b) (4)

Table 11.2 Summary of Incremental Design Changes - previously implemented on marketed device

Scope	Description	Reason for Change
Clip Feeding and Forming	Etched Line of Demarcation	<p>The instrument jaws are designed to passively close when the instrument is inserted through the trocar cannula. In order for the jaws to fully reopen, the instrument must be inserted far enough such that the inner diameter of the cannula is no longer pushing the jaws closed.</p> <p>The predicate device used a material interface as a line of demarcation. The shaft component has been modified to include an etched line of demarcation. The etched line further enhances visualization that the device has been inserted far enough past the end of the trocar to allow the jaws to reopen.</p>
Clip Feeding	Advancer-Clip Interface	<ul style="list-style-type: none"> • In order to accomplish the enhanced feeding, the advancer face and height increased dimension to provide increased surface area with the clip during the clip feeding into the jaws. • To accommodate the new advancer, the feed bar and tissue stop were changed to accommodate the dimension change. • (b) (4)
Jaw Opening	Change in Spring, Retraction of Forming System	(b) (4)

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510(k) Premarket Notification (Traditional) for Ligamax 5

Scope	Description	Reason for Change
Jaw Opening	Clip Indicator – Tactile Indicator for No-Clip Lockout	<p>A "jaws stuck closed" condition can be attributed to two primary conditions: a malformed clip caught at the proximal ends of the closed jaws or a broken feeder shoe tab resulting from firing through the no-clip lockout. The changes to enhanced feeding will address the "malformed clip" condition. To address the "firing through no-clip lockout" condition:</p> <p>(b) (4)</p>
Manufacturing Assembly	Feed Bar Change to Decrease Scrap Rate	<p>Dimensional change to the feed bar enhance manufacturing assembly and reduce scrap rate. Knock Out Pins were leaving remnant pin marks on the feed bar. To avoid interference between pin remnant mark and the mating component of the feed bar, a section of the feed bar was redesigned to relocate the knock out pins.</p>

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pg. 34

Section 12: Substantial Equivalence Discussion

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 Ethicon Endo-Surgery Ligamax 5 Endoscopic Multiple Clip Applier.

New device is compared to predicate devices

Predicate Device: K050344 Ligamax™ 5, cleared as Ligaclip 5 M/L

Subject Device: Ligamax 5, 5 mm Endoscopic Multiple Clip Applier

Does new device have same indications statement?

Yes. The indications statements are identical.

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

Yes. The subject device has the same technological characteristics as the predicate device such as the handle design, actuation trigger, rotation knob, shaft dimensions, visual no-clip indicator, tactile no-clip indicator, and jaws for forming ligating clips. Additionally, the feed-form sequence, clips, and indications have not changed. Compared to the marketed device, the Ligamax 5 subject device introduces no new patient-contacting materials. Biocompatibility was evaluated based on the ISO 10993-1 Standard and FDA Guidelines. Refer to Section 15 Biocompatibility.

Device enhancements have been made, and are discussed in Section 11.

Are the descriptive characteristics precise enough to ensure equivalence??

No. Some of the characteristics have been verified with Performance data, provided in Section 18.

Are performance data available to assess equivalence?

Yes, refer to Section 18.

Does performance data demonstrate equivalence?

Yes. Test methods to assess clip occlusion; clip security; force to squeeze handle to form a clip (force to fire); tactile indication force for "No-clip Lockout"; jaw reliability to form a clip over an existing structure; clip security in jaws; and clip count indicator reliability. Refer to Section 18 Performance Testing, Bench.

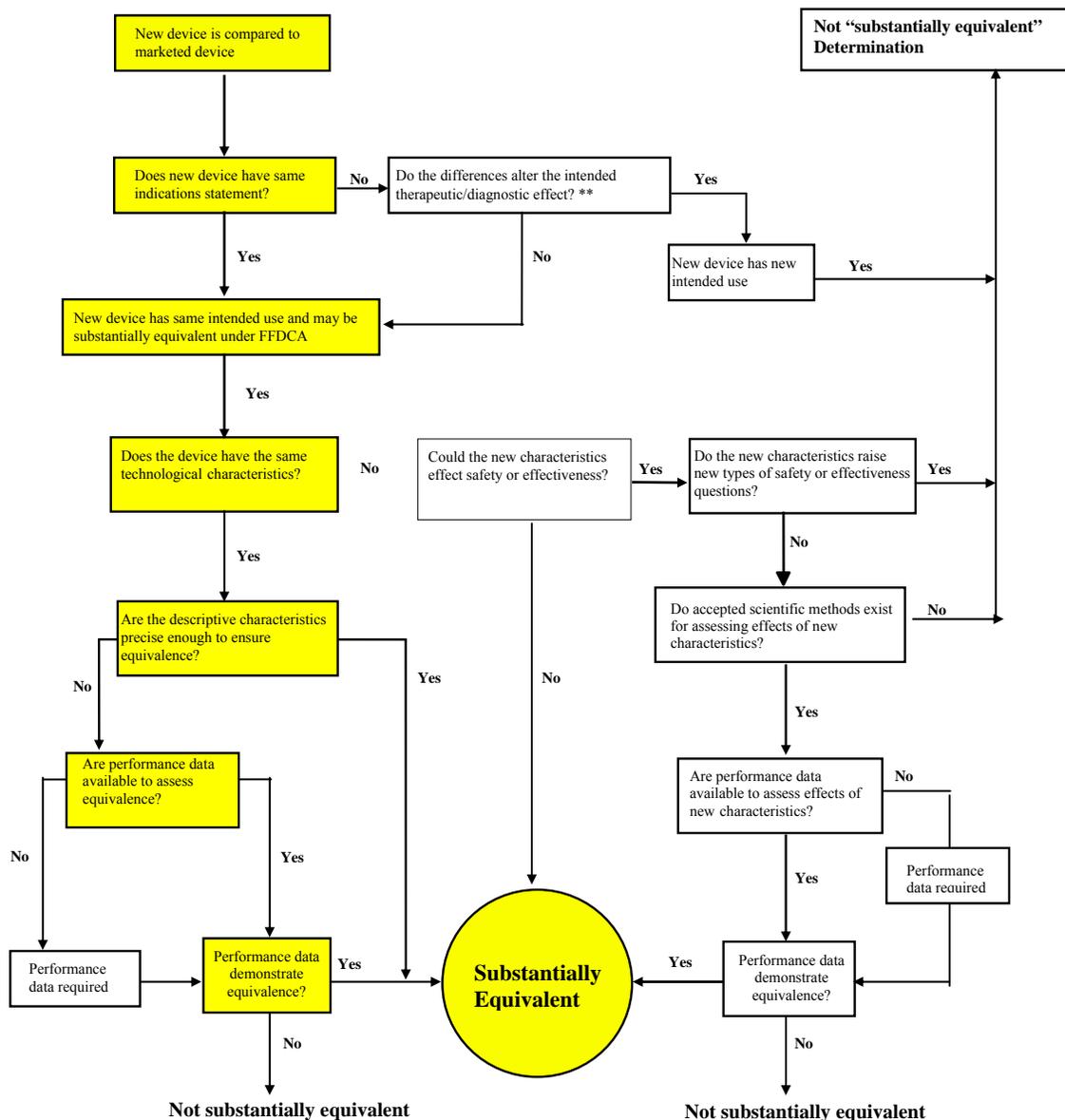
Substantially Equivalent Determination

In summary, Ligamax 5 is substantially equivalent to the predicate device.

In accordance with the Safe Medical Devices Act of 1990 (SMDA), a summary upon which this substantial equivalence determination is based is enclosed in Section 5 510(k) Summary. This summary may be released to the public.

The Substantial Equivalence Decision Making Process Decision Tree, with the path applicable to this submission highlighted, is provided on the following page in Figure 12.1.

Figure 12.1. 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 between marketed and “predicate” devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)'s, the Center’s classification files, or the literature.

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510(k) Premarket Notification (Traditional) for Ligamax 5

The Ligamax 5 indication and contraindication are identical to the predicate, refer to Table 12.1. The subject Ligamax 5 contains updated verbiage in the Package Insert in order to ensure clear, effective use. Please refer to Table 12.2 for specific changes. The bolded text identifies specific changes.

Table 12.1 Indication and Contraindications

Indication and Contraindications	Predicate	Ligamax 5
Indication: The 5 mm Endoscopic Multiple Clip Applier is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated.	Identical	Identical
Contraindication: 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.	Identical	Identical

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510(k) Premarket Notification (Traditional) for Ligamax 5

Table 12.2 Incremental Changes to the Package Insert Text

IFU Text	Predicate	Ligamax 5
Instruction Step 2	Remove the protective sleeve from the shaft of the instrument and discard.	Remove protective tip from the nose of the instrument.
Instruction Step 4	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.	Prior to loading a clip in the jaws and firing the instrument: ensure that the jaws are fully open by verifying that the line of demarcation between the jaws and the instrument shaft is past the distal end of the trocar cannula.
Instruction Step 5	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.	Prior to positioning the jaws around the tubular structure or vessel, load a clip into the jaws by partially squeezing the trigger approximately one-third of the total firing stroke.

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510(k) Premarket Notification (Traditional) for Ligamax 5

IFU Text	Predicate	Ligamax 5
Instruction Step 6	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.	Position the jaws with the preloaded clip completely around the tubular structure or vessel to be ligated. The structure to be ligated should be positioned against the apex of the clip. (Illustration 5) Note: The shaft can be rotated 360 degrees to facilitate visualization and accurate placement. Caution: Ensure that the clip is the correct size for the vessel or tubular structure being ligated. If the vessel or tubular structure is too large for the clip, remove the device and use an appropriately sized ligation device. Caution: Do not excessively twist or torque the instrument jaws when positioning or firing the instrument on a tubular structure or vessel. Excessive twisting or torqueing may result in clip malformation. (Illustration 6)

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510(k) Premarket Notification (Traditional) for Ligamax 5

IFU Text	Predicate	Ligamax 5
<p>Instruction Step 11</p>	<p>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 feature designed to increase the force required to close the trigger, thereby reducing the possibility that the empty jaws will be closed on a structure or vessel. Do not attempt to fire through the lockout. If the trigger is forced closed once the last clip lockout has engaged, the jaws may remain closed. If the jaws do not open when the trigger is released, pull the trigger outward to re-open the jaws. Do not re-fire the instrument.</p>	<p>When the 13th clip is fired, an orange bar will begin to appear in the indicator window on top of the device handle. (Illustration 8) The orange bar fills the indicator window when the final clip is fired. Note: The instrument contains a last clip lockout feature designed to increase the force required to close the trigger, thereby reducing the possibility that the empty jaws will be closed on a structure or vessel. Do not attempt to fire through the lockout. If force applied to trigger exceeds the last clip lockout, the jaws may remain closed. If the jaws do not open when the trigger is released, pull the trigger outward to re-open the jaws. Do not re-fire the instrument.</p>
<p>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</p>	<p>Located in Step 9</p>	<p>Located in Step 12</p>

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510(k) Premarket Notification (Traditional) for Ligamax 5

IFU Text	Predicate	Ligamax 5
Warnings and Precautions: Do not attempt to fire through the last clip lockout. Closing the instrument's jaws over a vessel or structure without a clip could result in damage to the vessel or structure.	Discussed in Step 11	Located in Step 11 and Warnings and Precautions
Warnings and Precautions: Dispose of all opened instruments whether used or unused.	Not present	Located at the end of Warnings and Precautions

* Please note that other minor verbage, grammar and punctuation were adjusted to enhance readability.

The table below provides a detailed side-by-side comparison of the proposed and predicate devices with respect to technology and device performance.

Table 12.3 Device Comparison Table: Technology and Performance Specifications

Characteristic	Subject Device Description	Predicate Device, K050344
Similarities		
Basic Clip Geometry	Apex and knee geometry, also known as traditional barn shape	Identical
Clip Aperture	(b) (4)	Identical
Clip Closed Length	(b) (4)	Identical
Clip Crimp Pads	Crimp pads allow instrument jaws to concentrate force near the clip apex, and fully from the clip.	Identical
Clip Cross Section	(b) (4)	Identical
Clip Material	(b) (4)	Identical
Clip Pattern	(b) (4)	Identical
Number of Preloaded Clips	15	Identical
Shaft Length	33 cm	Identical
Shaft Diameter	5.5 mm	Identical
Cholangio-click	Click signals that a clip has been partially formed to secure a Cholangiogram catheter	Identical
Clip Indicator	Indicator becomes progressively more visible when 3 or fewer clips remain in the device	Identical
Audible and tactile feedback	Ratchet or click sound during clip loading and the “cholangio click” portion of the firing sequence.	Identical
Feed-Form Sequence (user interface)	The device is ready for use upon remove from the package. To feed a clip into the instrument jaws, the trigger is squeezed approximately one-third of the firing stroke. The fed clip in the jaws can now be placed over the targeted structure or vessel. To form the clip onto the targeted structure or vessel, the trigger is fully squeezed toward the instrument handle until it touches the handle.	Identical
Trocar Compatibility	Jaws collapse passively during insertion, but reopen after clearing the distal tip of the trocar cannula. This enables 5 mm trocar insertions.	Identical
Rotation Knob	Allows the shaft to move 360°	Identical

Characteristic	Subject Device Description	Predicate Device, K050344
Overload Mechanism	Prevents excessive force applied to jaws if jaws are fired over an unintended structure, maintains jaw reliability	Identical
Handle and Trigger Ergonomics	Conventional pistol-grip configuration with actuation "firing" trigger	Identical
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° in either direction.	Identical
Shelf Life	5 years	Identical
Sterilization Process	Gamma Irradiation, [REDACTED] (b) (4) sterility assurance level (SAL).	Identical
Differences		
Jaw Aperture	[REDACTED] (b) (4)	[REDACTED]
Line of Demarcation, on distal end of the shaft near the jaws	Etched Line	Line distinguished by 2 materials meeting in a line
Force to fire through the Tactile "No-clip Lockout" Indicator	[REDACTED] (b) (4)	[REDACTED] (b) (4)

Section 13: Proposed Labeling

This section contains labeling for Ethicon Endo-Surgery Ligamax™ 5. The labeling includes: modified Ligamax 5 Package Insert and the Predicate Ligamax 5 Package Insert. There have been no changes to the Ligamax 5 Primary Label (also known as the Tyvek® label) or the carton.

Ligamax 5 Package Insert

The Package Insert will be supplied in multiple languages. This section includes only the English portion of the subject device Package Insert.

LIGAMAX⁵

5 mm Endoscopic Multiple Clip Applier

Multi-applicateur endoscopique de clips de 5 mm

5 mm endoskopischer Multiclipapplikator

Applicatore multiplo endoscopico di clip da 5 mm

Aplicador endoscópico de múltiplos clips de 5 mm

Endoaplicador de clips múltiple de 5 mm

5 mm endoskopische multicliptang

5 mm endoskopisk multiclips

5 mm:n endoskoopinen klipsien

kiinnitysinstrumentti

Ενδοσκοπική λαβίδα απολίνωσης πολλαπλών κλιπ 5 mm

5 mm endoskopisk multiclipsapplikator

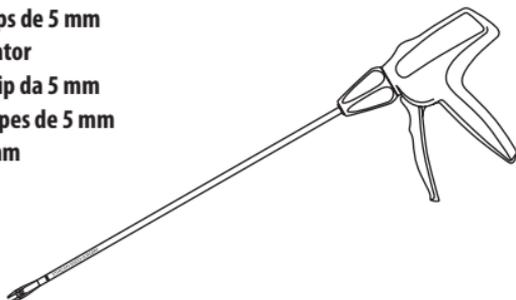
Endoskopowa klipsownica o średnicy 5 mm do wielokrotnego zakładania klipsów

5 mm-es endoszkópos többszörös kapocsbehelyező

Endoskopický vícenásobný aplikátor sponek o průměru 5 mm

Endoskopický aplikátor viacerých svoriek priemeru 5 mm

5 mm 内镜式连发施夹器



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 LIGAMAX⁵ – 5 mm Endoscopic Multiple Clip Applier. It is not a reference to ligation techniques.

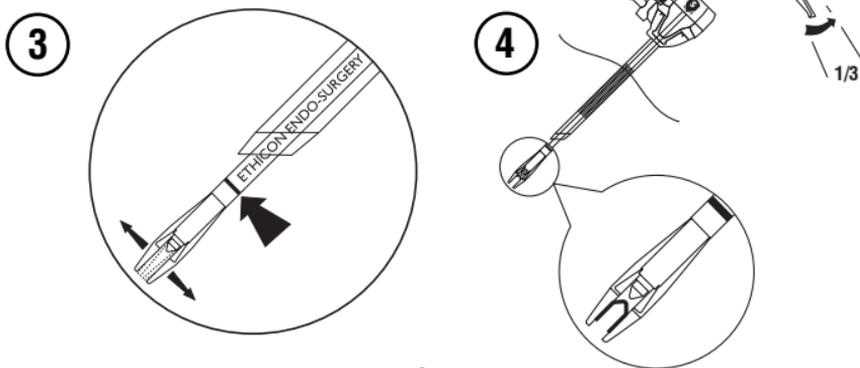
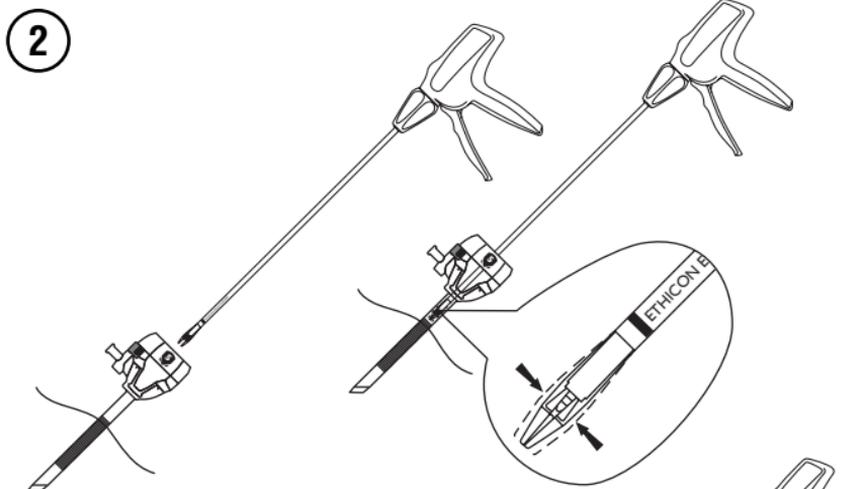
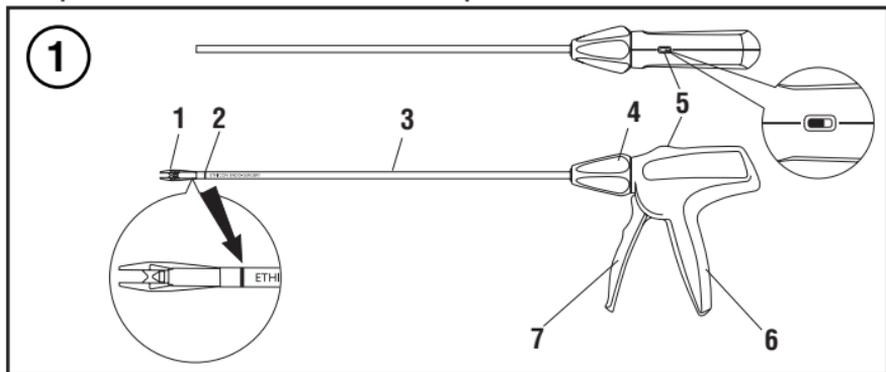
LIGAMAX is a trademark of Ethicon Endo-Surgery.



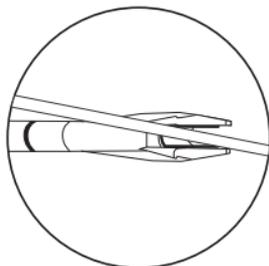
ETHICON ENDO-SURGERY, LLC

a Johnson & Johnson company

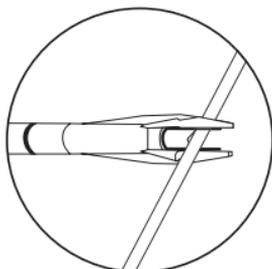
Instructions, Instructions, Gebrauchsanweisung, Istruzioni, Instruções, Instrucciones,
Gebruiksaanwijzing, Brugsvejledning, Ohje, Οδηγίες, Bruksanvisning, Instrukcja,
Utasítások, Návod k použití, Návod, 使用说明



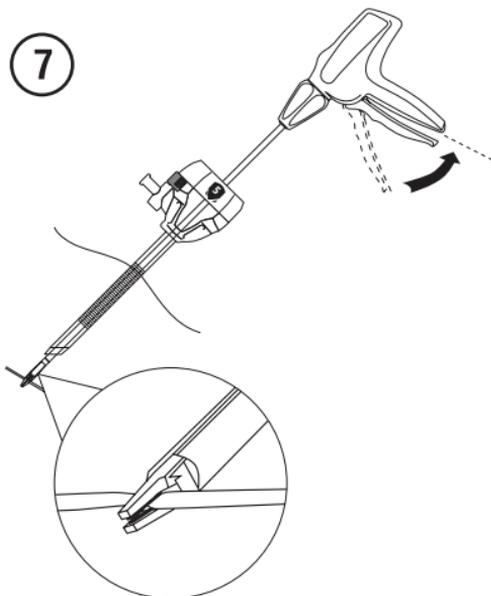
5



6



7



8



Indications

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

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.

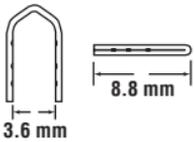
Product Code	Shaft Diameter	Clip Size/ No. of Clips	Clip Dimensions	Overall Shaft Length (approx.)
EL5ML	5.5 mm	Medium/Large 15		33 cm

Illustration and Nomenclature (Illustration 1)

- | | |
|------------------------|---------------------|
| 1. Jaws | 5. Indicator Window |
| 2. Line of Demarcation | 6. Handle |
| 3. Shaft | 7. Trigger |
| 4. Rotation Knob | |

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 protective cap from the jaws of the instrument.
- Insert the clip applier through an appropriately-sized trocar. The empty jaws will passively collapse as they are inserted through a 5 mm trocar (Illustration 2) and reopen when completely through the trocar. (Illustration 3)

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 before inserting the device through the trocar.

- Prior to loading a clip in the jaws and firing the instrument: ensure that the jaws are fully open by verifying that the line of demarcation between the jaws and the instrument shaft is past the distal 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 in a smooth continuous motion for approximately one-third of the total firing stroke. (Illustration 4)

Caution: Inspect the jaw tips to ensure the clip is fully advanced in the jaws. (Illustration 4)

- Position the jaws with the preloaded clip completely around the tubular structure or vessel to be ligated. The structure to be ligated should be positioned against the apex of the clip. (Illustration 5)
Note: The shaft can be rotated 360 degrees to facilitate visualization and accurate placement.

Caution: Ensure that the clip is the correct size for the vessel or tubular structure being ligated. If the vessel or tubular structure is too large for the clip, remove the device and use an appropriately sized ligation device.

Caution: 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. (Illustration 6)

- 7 Complete the firing cycle by squeezing the trigger until it stops against the handle to completely form the clip on the targeted structure or vessel. (Illustration 7)

Caution: The trigger must be fully squeezed against the handle to ensure complete clip formation.

- 8 After firing, fully release the trigger.

Note: A clip will not be loaded in the jaws until the trigger is squeezed again.

- 9 Check to ensure that each clip has been securely placed around the tissue being ligated.

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 the 13th clip is fired, an orange bar will begin to appear in the indicator window on top of the device handle. (Illustration 8) The orange bar fills the indicator window when the final clip is fired.

Note: The instrument contains a last clip lockout feature designed to increase the force required to close the trigger, thereby reducing the possibility that the empty jaws will be closed on a structure or vessel. Do not attempt to fire through the lockout. If force applied to trigger exceeds the last clip lockout, the jaws may remain closed. If the jaws do not open when the trigger is released, pull the trigger outward to re-open the jaws. Do not refire the instrument.

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

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.

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 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 in the jaws, fully squeeze the trigger against the handle, then fully release the trigger to release the clip from the jaws before inserting the device through the trocar.
- Inspect the jaw tips to ensure the clip is fully advanced in the jaws of the instrument.
- Ensure that each clip is securely and completely positioned around the tissue being ligated before completion of firing cycle.
- 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.
- Do not attempt to fire through the last clip lockout. Closing the instrument's jaws over a vessel or structure without a clip could result in damage to the vessel or structure.
- Do not attempt to remove closed jaws from the structure or vessel. This could result in damage to the structure or vessel. Pull the trigger outward to re-open the jaws.
- 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. Firing the instrument over another clip or instrument can also damage a properly deployed clip, disrupt related vessels and structures, and damage the instrument.
- 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.
- Dispose of all opened instruments whether used or unused.
- This device is packaged and sterilized 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 that 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 LIGAMAX⁵ – 5 mm Endoscopic Multiple Clip Applier is supplied sterile for single patient use. Discard after use.

LIGAMAX⁵

Multi-applicateur endoscopique de clips de 5 mm

Prière de lire attentivement toutes les informations.

Le non-respect du mode d'emploi risque d'entraîner des conséquences chirurgicales graves, comme un échec de la ligature.

Important : Cette notice a pour but de donner des instructions sur l'utilisation du multi-applicateur endoscopique de clips de 5 mm LIGAMAX⁵. Elle ne constitue pas une référence sur les techniques de ligature.

LIGAMAX est une marque commerciale d'Ethicon Endo-Surgery.

Indications

Le multi-applicateur endoscopique de clips de 5 mm est destiné à être utilisé sur des vaisseaux ou des structures tubulaires, lorsqu'une ligature au moyen d'un clip métallique est indiquée.

Contre-indications

- NE PAS utiliser cet instrument pour des ligatures de trompes à des fins contraceptives.
- NE PAS utiliser cet instrument sur des vaisseaux ou des structures tissulaires sur lesquels des clips métalliques de ligature ne sont normalement pas utilisés.

Description du dispositif

Le multi-applicateur endoscopique de clips de 5 mm est un instrument stérile à n'utiliser que sur un seul patient lors d'une seule et même intervention, conçu pour effectuer des ligatures au travers d'un trocart de

	<p>Sterilized by Irradiation. Sterility Guaranteed Unless Package Opened or Damaged. Do Not Resterilize. Stérilisé par irradiation. Stérilité garantie si l'emballage n'a pas été ouvert ou endommagé. Ne pas restériliser. Strahlensterilisiert. Nicht verwenden, wenn die Sterilverpackung geöffnet oder beschädigt ist. Nicht reesterilisieren. Sterilizzato con radiazioni. Sterilità garantita, a meno che la confezione non venga aperta o danneggiata. Non risterilizzare. Esterilizado por irradiación. Esterilização garantida excepto se a embalagem estiver aberta ou danificada. Não reesterilizar. Estéril por radiación. Esterilización garantizada mientras el envase esté íntegro. No reesterilizar. Gesteriliseerd met straling. Steriliteit gegarandeerd tenzij de verpakking is geopend of beschadigd. Niet opnieuw steriliseren. Steriliseret ved stråling. Garanteret sterilt, med mindre pakken er åbnet eller beskadiget. Må ikke gensteriliseres. Steriloitu säteilyttämällä. Tuote on steriili, kun pakkaus on avaamaton ja ehjä. Ei saa steriloida uudestaan. Αποστειρωμένοι με ακτινοβολία. Η στερότητα είναι εγγυημένη εφόσον δεν ανοιχθεί η συσκευασία ή δεν προκληθεί ζημιά σε αυτήν. Μην επαναποστειρώνετε. Steriliserad med bestrålning. Steriliteten garanteras under förutsättning att förpackningen inte är öppnad eller skadad. Får ej omsteriliseras. Urządzenie/sprzet sterylizowane promieniowaniem. Jałowość gwarantowana pod warunkiem, że opakowanie nie zostało otwarte lub uszkodzone. Nie sterylizować ponownie. Besugárzással sterilizálva. A sterilitása addig garantálható, amíg ki nem nyitják, illetve meg nem sérül a csomagolás. Tilos újra sterilizálni! Sterilizace se provádí ozářením. Sterilnost je zaručena, pokud balení není otevřené nebo poškozené. Nástroj znovu nesterilizujte. Sterilizované ožarováním. Sterilita je zaručená, ak nie je otvorený alebo poškodený obal. Neresterilizujte. 辐射灭菌。 如果产品包装未开封或者未被破损，保证无菌。不得再次灭菌。</p>	
	<p>See Instructions For Use Voir notice d'utilisation Bitte Gebrauchsanweisung beachten Vedere le istruzioni per l'uso Ver Instruções de Uso Ver instrucciones de uso Zie gebruiksaanwijzing Se brugsvejledningen</p>	<p>Katso käyttöohjeet Διαβάστε τις Οδηγίες Χρήσεως Se bruksanvisning Zobacz Instrukcja użytkowania Lásd a használati útmutatót Prostudujte návod k použití Prečítajte si návod na použitie 参见使用说明</p>
	<p>Single Patient Use À utiliser sur un seul patient Einweg-Instrument, nur für den Einsatz bei einem Patienten Per l'uso su un singolo paziente Para ser utilizado num único doente Uso en un solo paciente Voor gebruik bij één pati Til anvendelse på én patient</p>	<p>Potilaskohtainen Χρήση σε έναν μόνον ασθενή Endast för en patients bruk Do użytku u jednego pacjenta Egyetlen betegnél használható fel Nástroj je určený pouze pro jednoho pacienta Určené iba pre jedného pacienta 单个患者使用</p>

	Lot N° de lot Ch. -B. Lotto N° do lote N° de lote Lotnr. Parti	Erän koodi Αρ. παρτίδας Batchnummer Numer partii produkcyjnej Tétel Šarže Šarža 批号
	Use Until Date À utiliser avant Verw. bis Utilizzare entro Validade A utilizar antes de Gebruik vóór Holdbar til angivne dato	Käytettävä viimeistään Χρησιμοποιείτε μέχρι την Använd före Koniec okresu przydatności do użytku A feltüntetett dátumig használható fel Použit do data Použitelné do 有效期
	<p>Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.</p> <p>Attention : Aux États-Unis, selon la loi fédérale, ce produit est exclusivement vendu sur prescription médicale.</p> <p>Achtung: Laut Gesetz darf dieses Instrument in den USA nur an einen Mediziner oder eine in seinem Auftrag handelnde Person verkauft werden.</p> <p>Attenzione: la legge federale americana consente la vendita di questo dispositivo solo dietro richiesta medica.</p> <p>Attenzione: vendita riservata esclusivamente a Farmacie, Enti Ospedalieri, Case di Cura.</p> <p>Atenção: A lei federal (dos Estados Unidos) só permite a venda deste dispositivo a médicos ou sob receita destes.</p> <p>Atención: la ley federal de EE. UU. impone que este producto sólo puede ser vendido por un médico o bajo prescripción médica.</p> <p>Waarschuwing: De Federale wetgeving (in de VS) eist dat dit apparaat uitsluitend door of in opdracht van een arts wordt verkocht.</p> <p>Forsigtig: I henhold til gældende lov må denne anordning kun sælges til eller bruges af en læge.</p> <p>Varoitus: Yhdysvaltain lain mukaan tämän tuotteen saa myydä vain lääkäri tai lääkärin määräyksestä.</p> <p>Προσοχή: Το ομοσπονδιακό δίκαιο των ΗΠΑ περιορίζει την πώληση του εργαλείου αυτού μόνον από ιατρούς ή κατόπιν εντολής ιατρού.</p> <p>Varning: Enligt amerikansk lag får detta instrument endast säljas till läkare eller på läkares anmodan.</p> <p>Przestroga: Prawo federalne (USA) zezwala na sprzedaż tego urządzenia wyłącznie lekarzowi lub na jego zamówienie.</p> <p>Figyelem! Az USA szövetségi törvényei értelmében az eszköz csak orvos megrendelésére értékesíthető.</p> <p>Upozornění: Podle federálních zákonů USA je prodej tohoto zařízení omezen na prodej v lékárnách nebo na lékařský předpis.</p> <p>Pozor: Podľa federálnych zákonov (v USA) sa toto zariadenie smie predávať iba lekárom alebo na lekársky predpis.</p> <p>注意：联邦（美国）法律只允许医师销售或订购该器械。</p>	

	<p> Manufacturer Fabricant Hersteller Produttore Fabricante Fabricant Fabrikant Producent </p> <p> Valmistaja Κατασκευαστής Tillverkare Producent Gyártó Výrobce Výrobca 制造商 </p>
	<p> Authorized Representative in the European Community Représentant autorisé dans la Communauté européenne Bevollmächtigter in der Europäischen Gemeinschaft Distributore autorizzato per la Comunità Europea Representante autorizado na Comunidade Europeia Representante autorizado en la Comunidad Europea Bevoegd vertegenwoordiger bij de Europese Gemeenschap Autoriseret repræsentant i det europæiske fællesskab Valtuutettu edustaja Euroopan yhteisön alueella Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα Auktoriserad representant i Europeiska gemenskapen Autoryzowany przedstawiciel w Unii Europejskiej Az Európai Közösség meghatalmazott képviselője Autorizovaný zástupce v Evropském společenství Autorizovaný zástupca EU 欧共体内授权代理 </p>
	<p> Authorized Representative in the USA Représentant autorisé aux Etats-Unis Bevollmächtigter in den USA Rappresentante autorizzato per gli Stati Uniti Representante autorizado nos EUA Representante autorizado en EE. UU. Bevoegd vertegenwoordiger in de VS Bemyndiget repræsentant i USA Valtuutettu edustaja Yhdysvalloissa Εξουσιοδοτημένος αντιπρόσωπος στις ΗΠΑ Auktoriserad representant i USA Autoryzowany przedstawiciel w Stanach Zjednoczonych Ameryki Meghatalmazott képviselő az Egyesült Államokban Autorizovaný zástupce v USA Autorizovaný zástupca v USA 美国授权代理人 </p>



P40499P04

REF

ELSML



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ETHICON ENDO-SURGERY, LLC

a *Johnson & Johnson* company



ETHICON ENDO-SURGERY, LLC
Guaynabo, Puerto Rico 00969 USA

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Rev. 2009-09

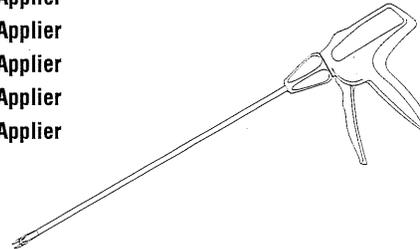
P40499P04

Predicate Package Insert

This section includes the English portion of the Predicate Package Insert, for reference.

LIGACLIP® 5 M/L

- 5 mm Endoscopic Multiple Clip Applier**



- 5 mm Endoscopic Multiple Clip Applier**



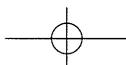
Please read all information carefully.

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.

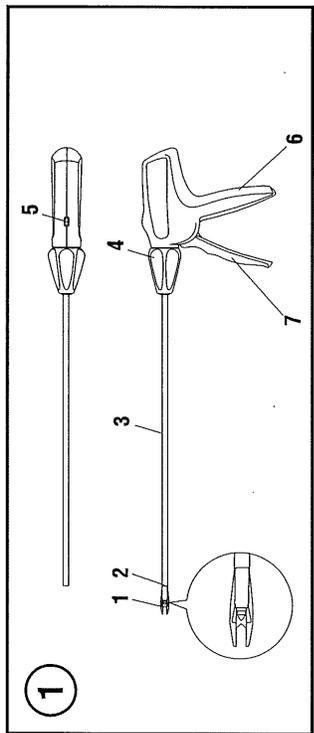


Instructions, Instructions, Gebrauchsanweisung, Istruzioni, Instruções, Instrucciones,
 Gebruiksaanwijzing, Brugsvejledning, Ohje, Οδηγίες, Bruksanvisning, Instrukcja,
 Utasítások, Návod k použití, Návod, 說明書

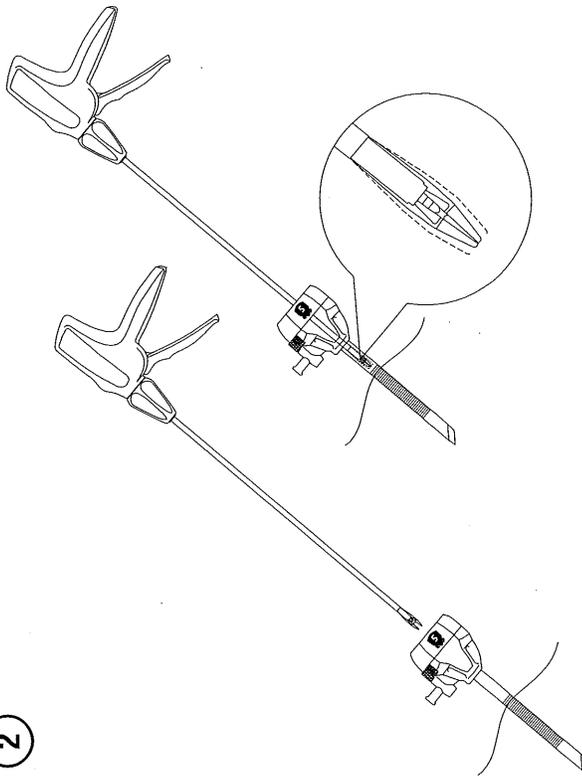


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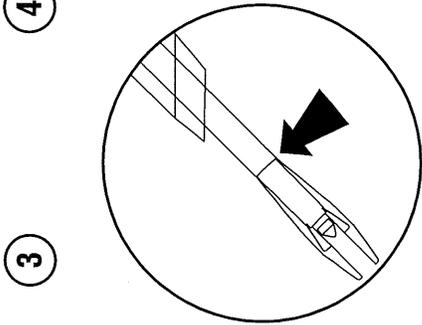
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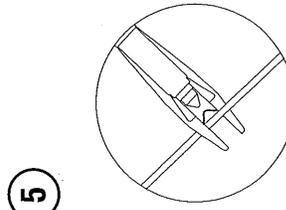


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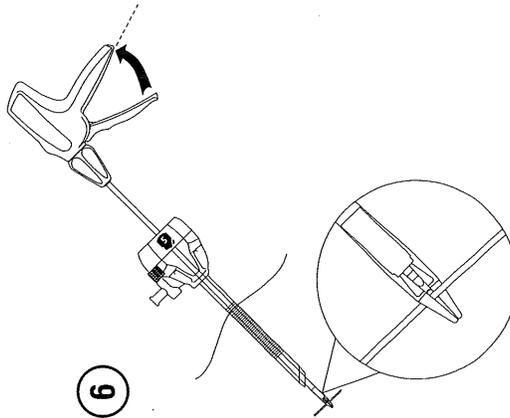
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English

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.

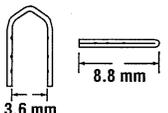
Product Code	Shaft Diameter	Clip Size/ No. of Clips	Clip Dimensions	Overall Shaft Length (approx.)
EL5ML	5.5 mm	Medium/Large 15		33 cm

Illustration and Nomenclature (Illustration 1)

- | | |
|------------------|---------------------|
| 1. Jaws | 5. Indicator Window |
| 2. Demarcation | 6. Handle |
| 3. Shaft | 7. Trigger |
| 4. Rotation Knob | |

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

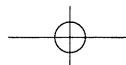
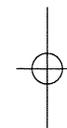
Warnings and Precautions

- 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, 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 grounding is not compromised. Do not immerse electro-surgical 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.



6
6

Section 14: Sterilization and Shelf Life

Sterilization

There have been no changes to the sterilization of Ligamax 5 from the predicate device.

The Ligamax 5 will be sterilized by Cobalt 60 irradiation. The device will be validated to

(b) (4)

The sterilization process will be validated and the sterilization dose will be established per the requirements of the following FDA recognized standards:

(b) (4)

The Ligamax 5 is intended for single patient use and is not intended to be reused or resterilized.

Packaging

The subject Ligamax 5 is packaged in a clear (b) (4) blister package with a heat-sealed preprinted Tyvek lid.

The predicate is packaged in either (b) (4) blister with a heat-sealed Tyvek lid or a (b) (4) with a heat-sealed Tyvek lid.

Three sealed (b) (4) blisters are placed in an (b) (4) sales unit carton. Four of the SBS sales unit cartons are placed in a corrugated shipper, same as the predicate.

Shelf Life

There have been no changes to the shelf life of Ligamax 5 from the predicate device.

The shelf life of the product is five years.

Section 15: Biocompatibility

There have been no new patient-contacting materials introduced to the Ligamax™ 5.

The Feeder Shoe component of this device was initially categorized as a Surface Component with Less Than 24 Hours of Skin Contact. Upon further evaluation, this component was reclassified as an Externally Communicating Component with Tissue or Bone Contact of Less Than 24 Hours (Limited Tissue Contact). The material itself has not changed. However, although only recently reclassified, this material had been tested to the more rigorous classification of Externally Communicating Component with Tissue or Bone Contact of Less Than 24 Hours.

Part Name	Subject Device Classification	Predicate Device Classification	Device Material
Feeder Shoe	Externally communicating component with tissue or bone contact of less than 24 hours. (Limited Tissue Contact)	Surface component with less than 24 hours of skin contact (Limited Surface Contact - Skin)	(b) (4) [REDACTED] previously cleared under K970720

The biocompatibility of materials used in Ligamax 5 was evaluated based on ISO 10993-1:2003 “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.” All tests were performed in accordance with FDA’s Good Laboratory Practice Standard.

Section 16: Software

This section does not apply; this device does not include software.

Section 17: Electromagnetic Compatibility and Electrical Safety

This section does not apply; this device does not include electronic components.

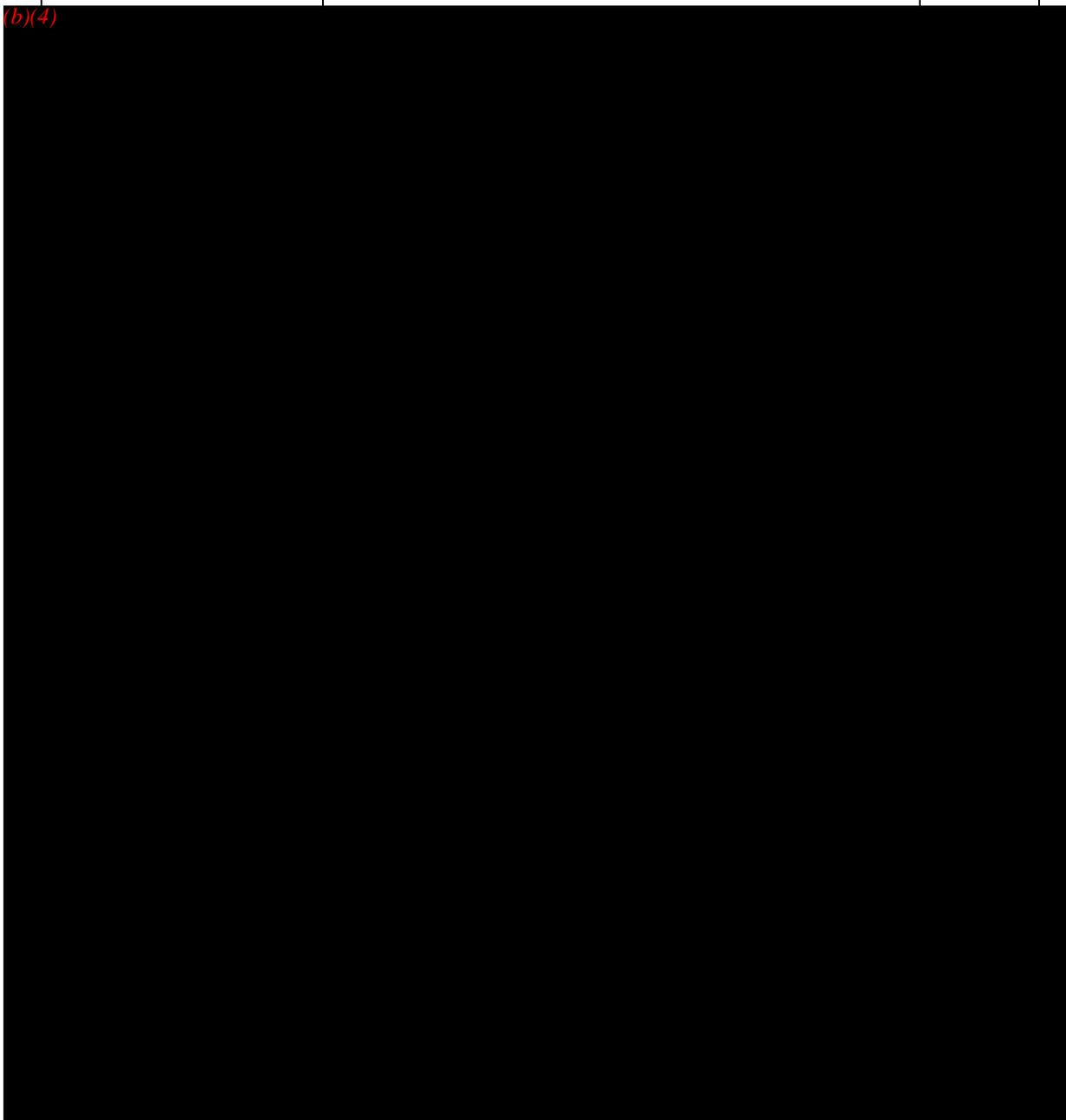
Section 18: Performance Testing – Bench

This section presents the bench testing used to evaluate and verify the performance of the Ethicon Endo-Surgery subject device Ligamax™ 5 Endoscopic Multiple Clip Applier. Bench verification test objectives, acceptance criteria, methods, and results are included. Test results show that the subject device and predicate device both meet the defined design requirements, which demonstrate substantial equivalence. Table 18.1 provides a summary of the performance testing. A summary of bench verification testing is provided on the following pages.

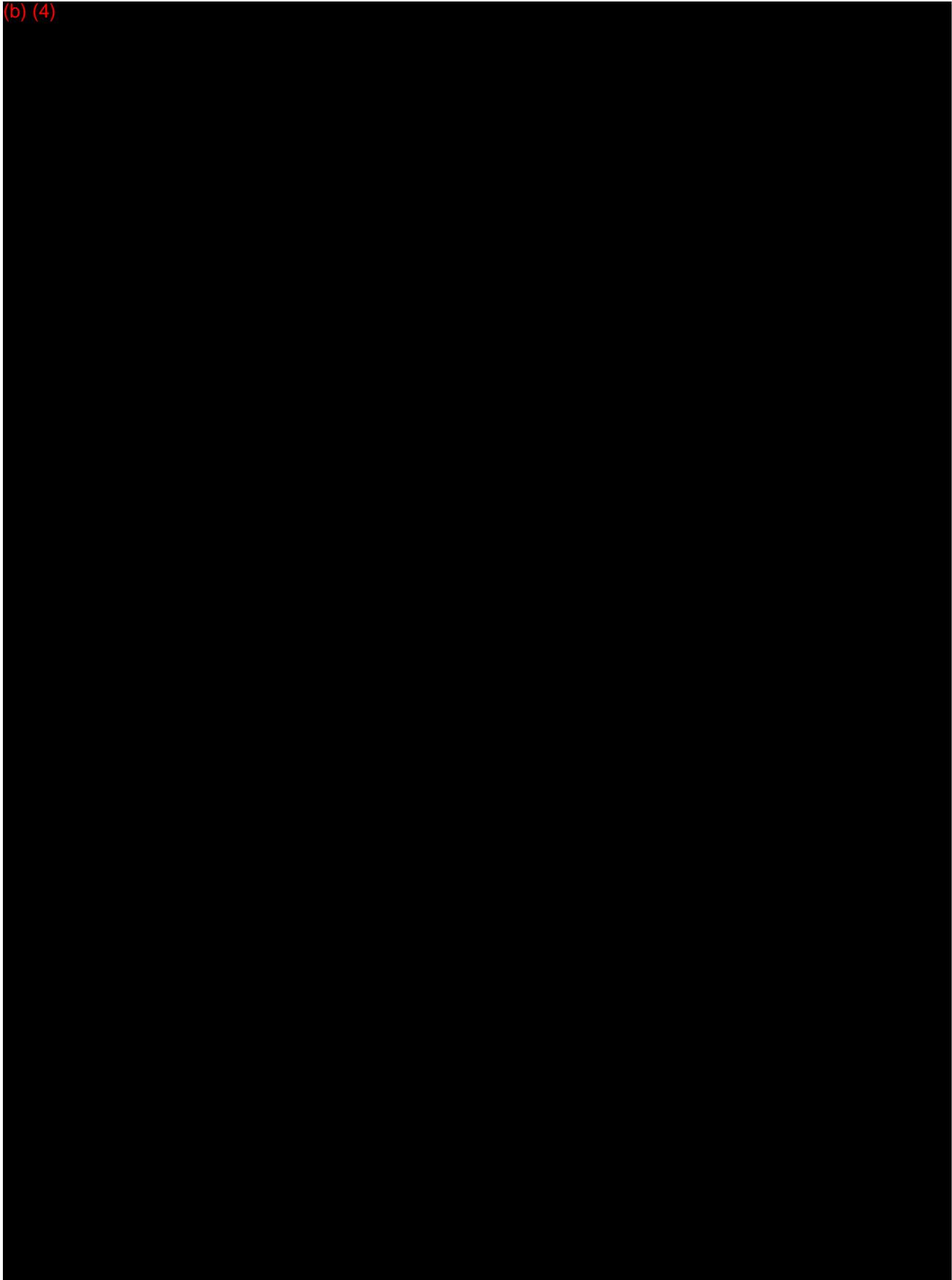
Table 18.1 Performance Test and Results

Purpose	Performance Test	Results
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(b) (4)



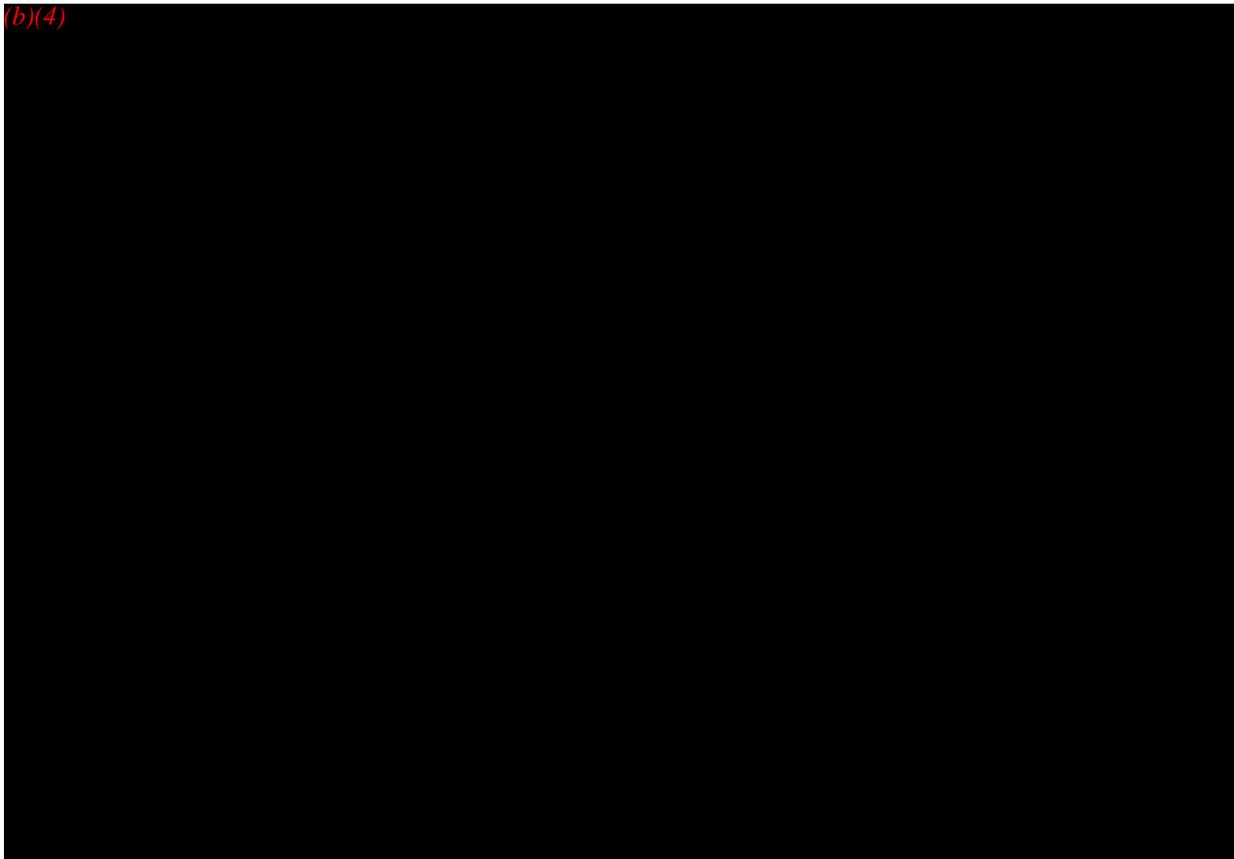
CONFIDENTIAL

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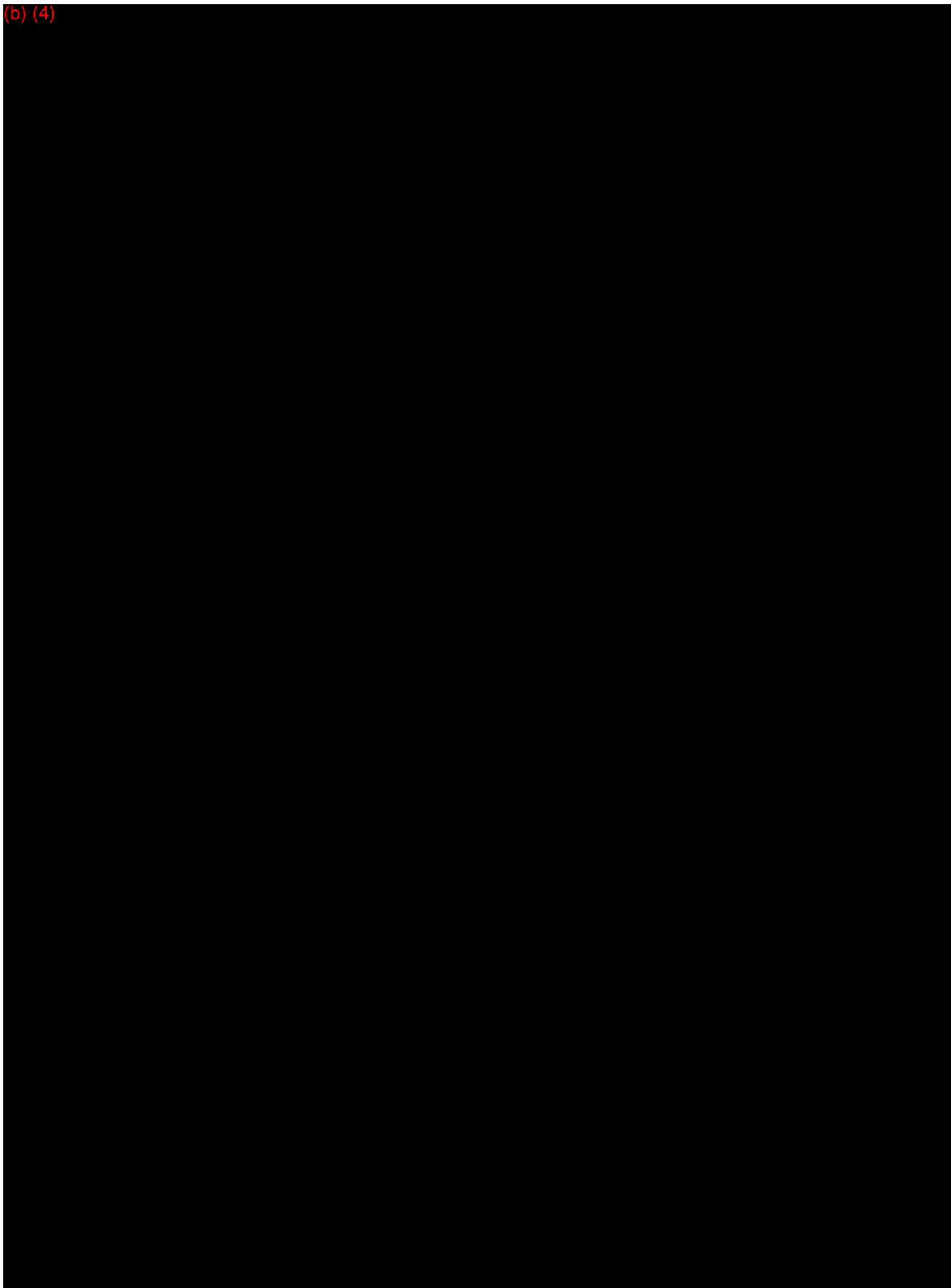
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Results and Discussion

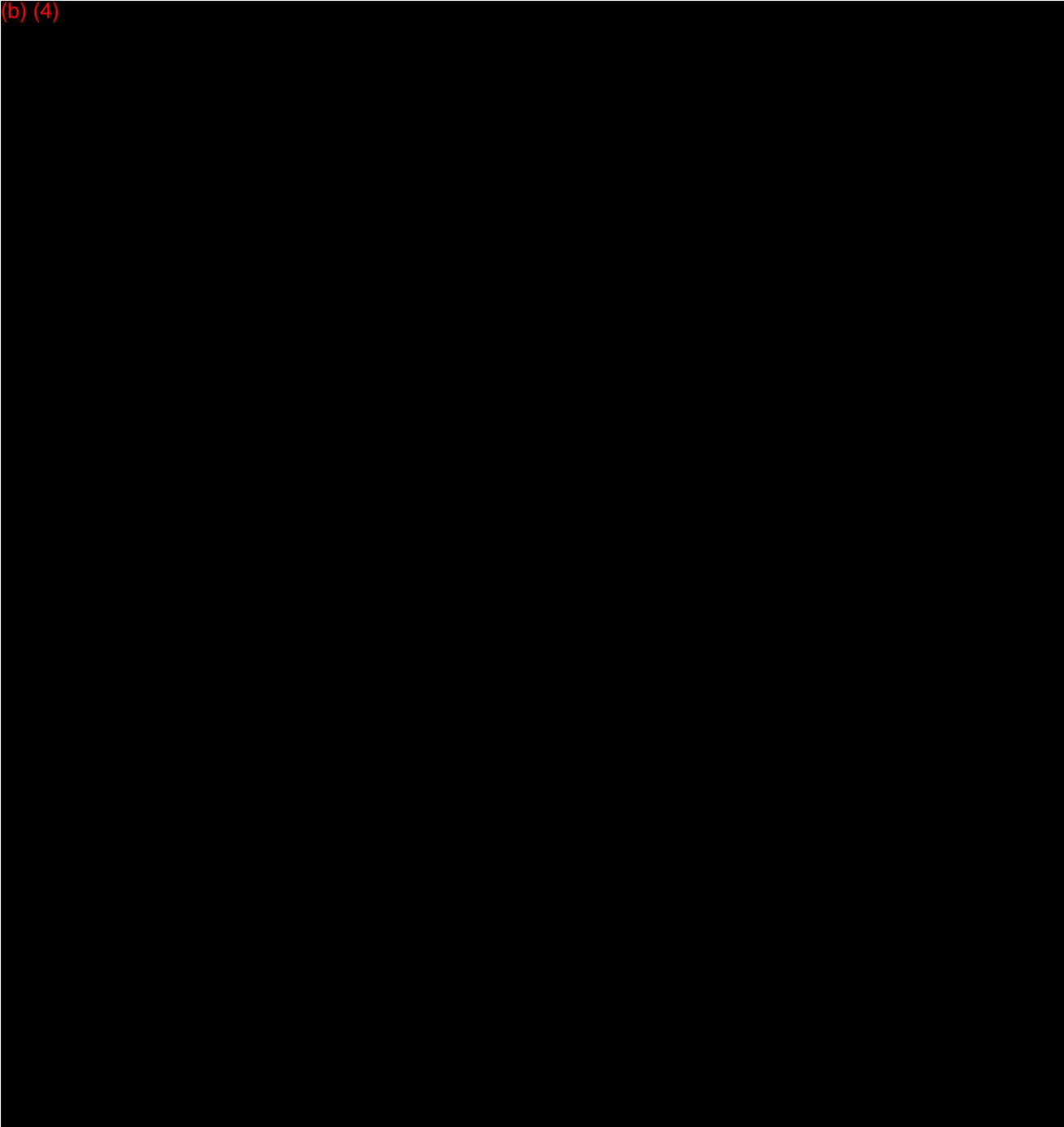
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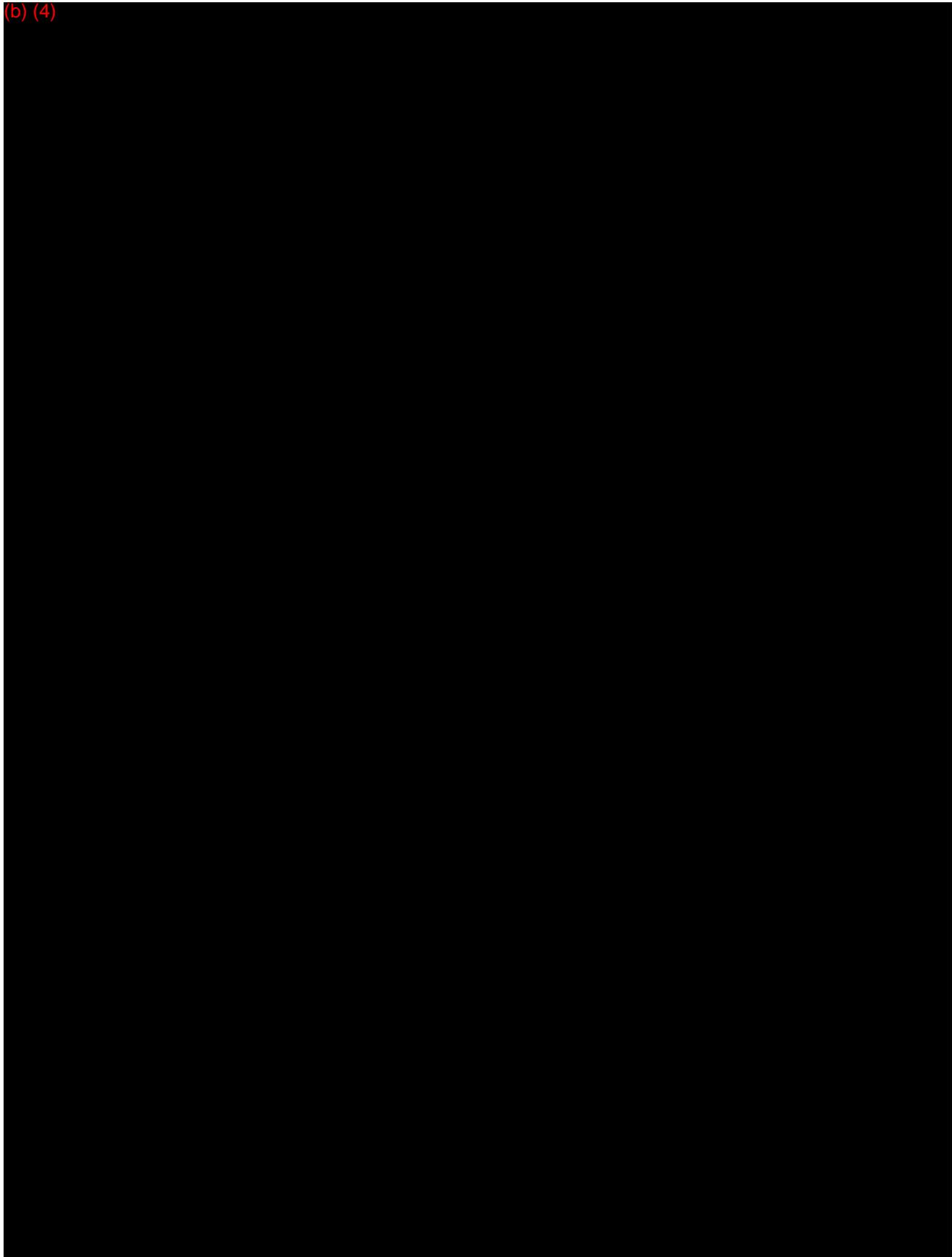
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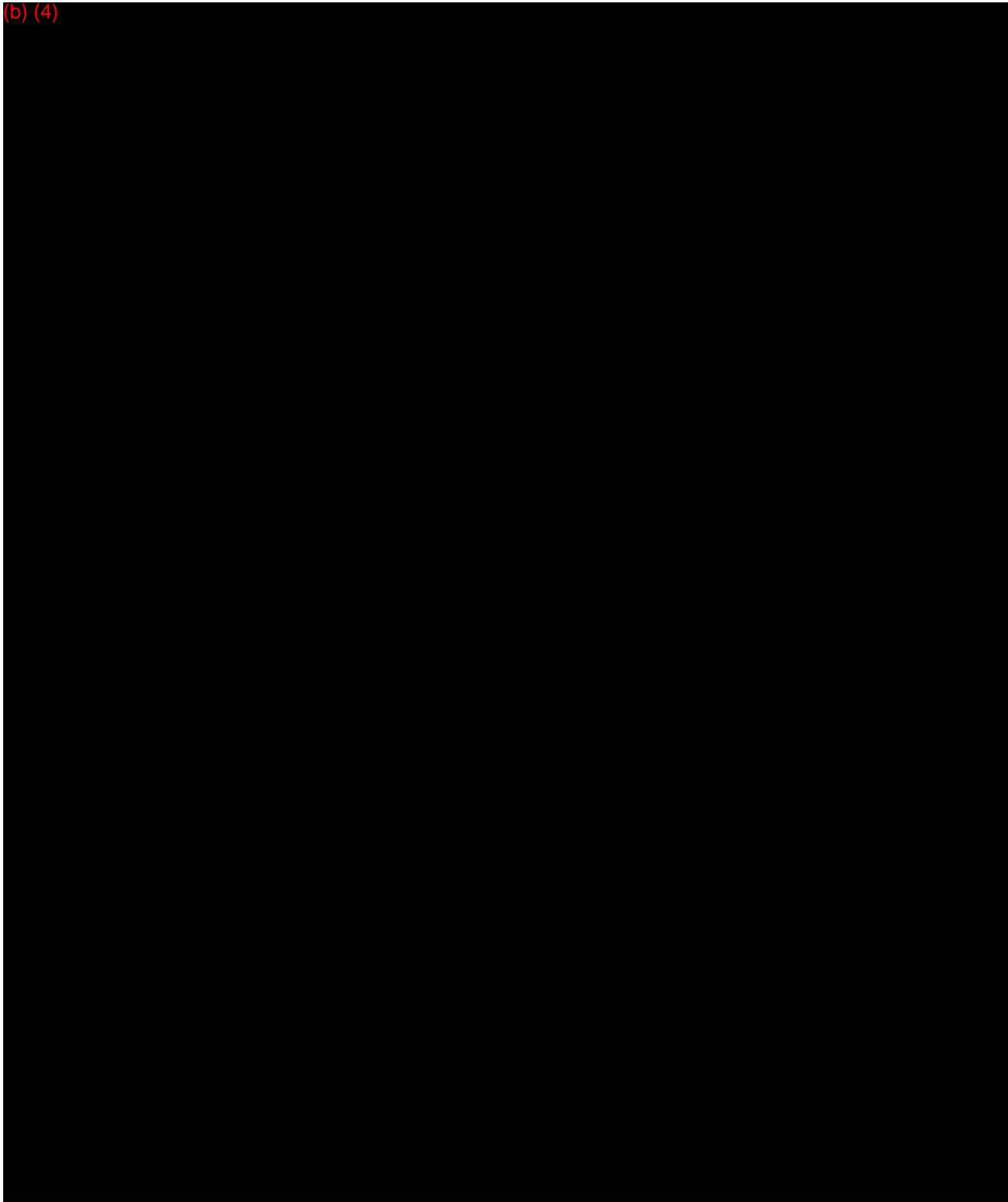
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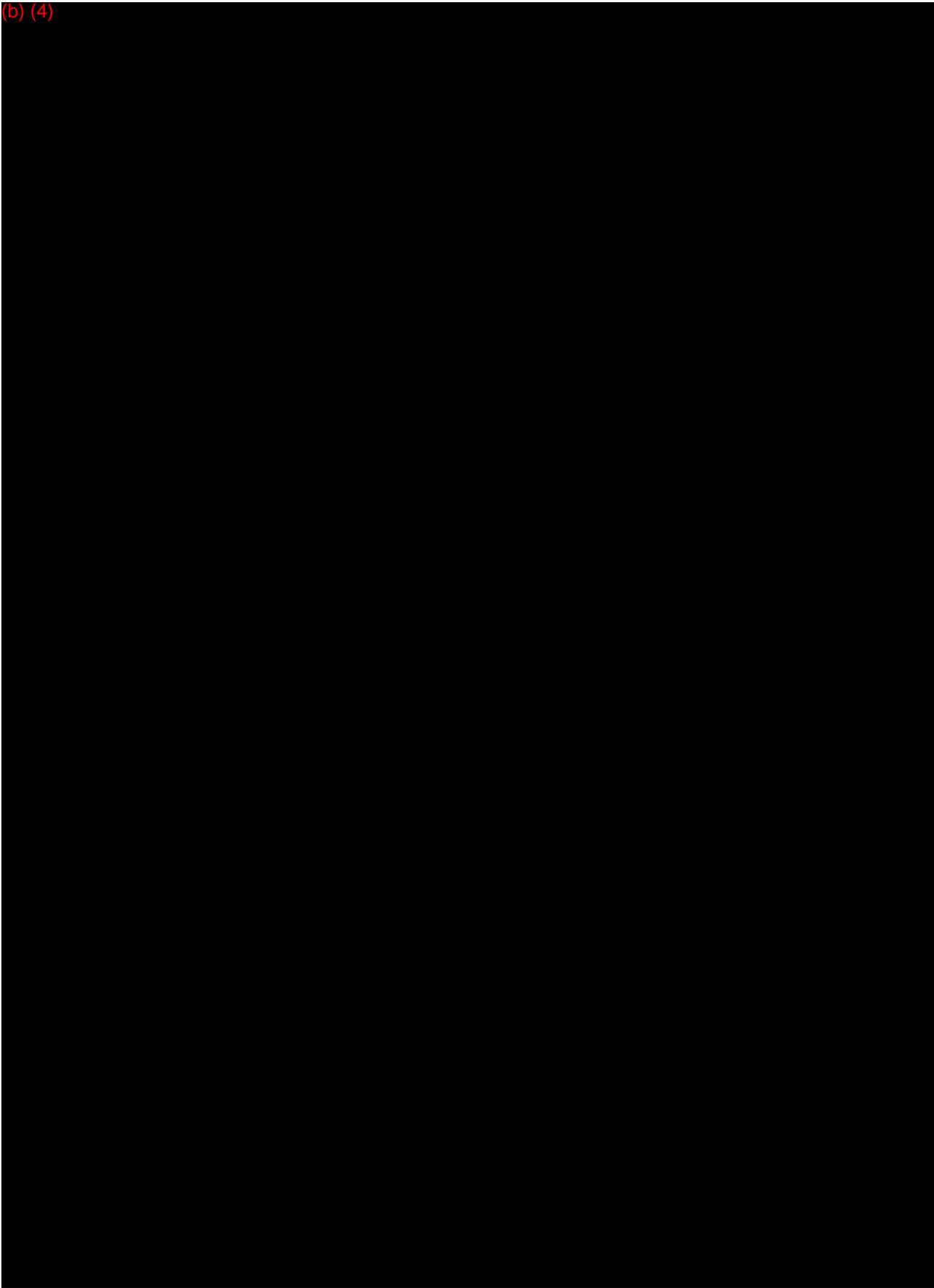
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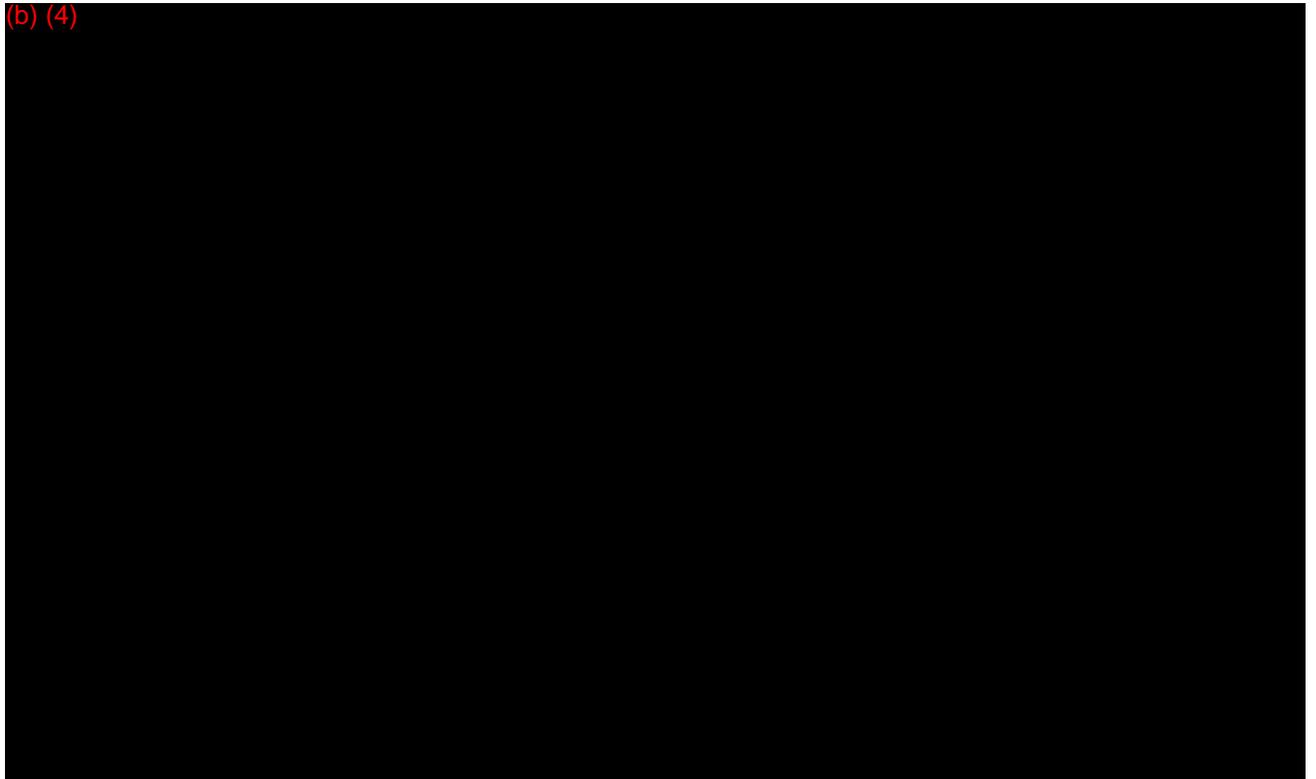
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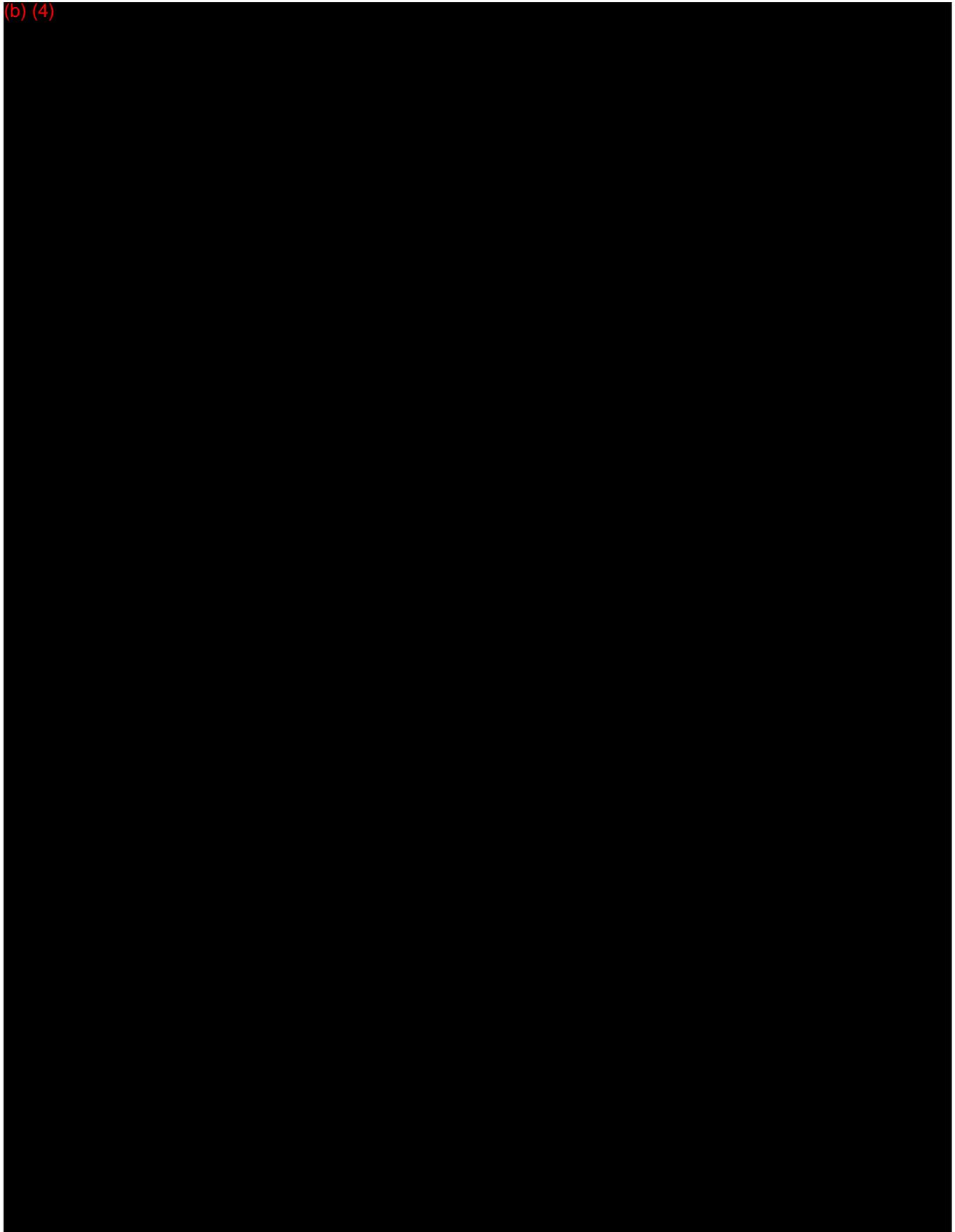
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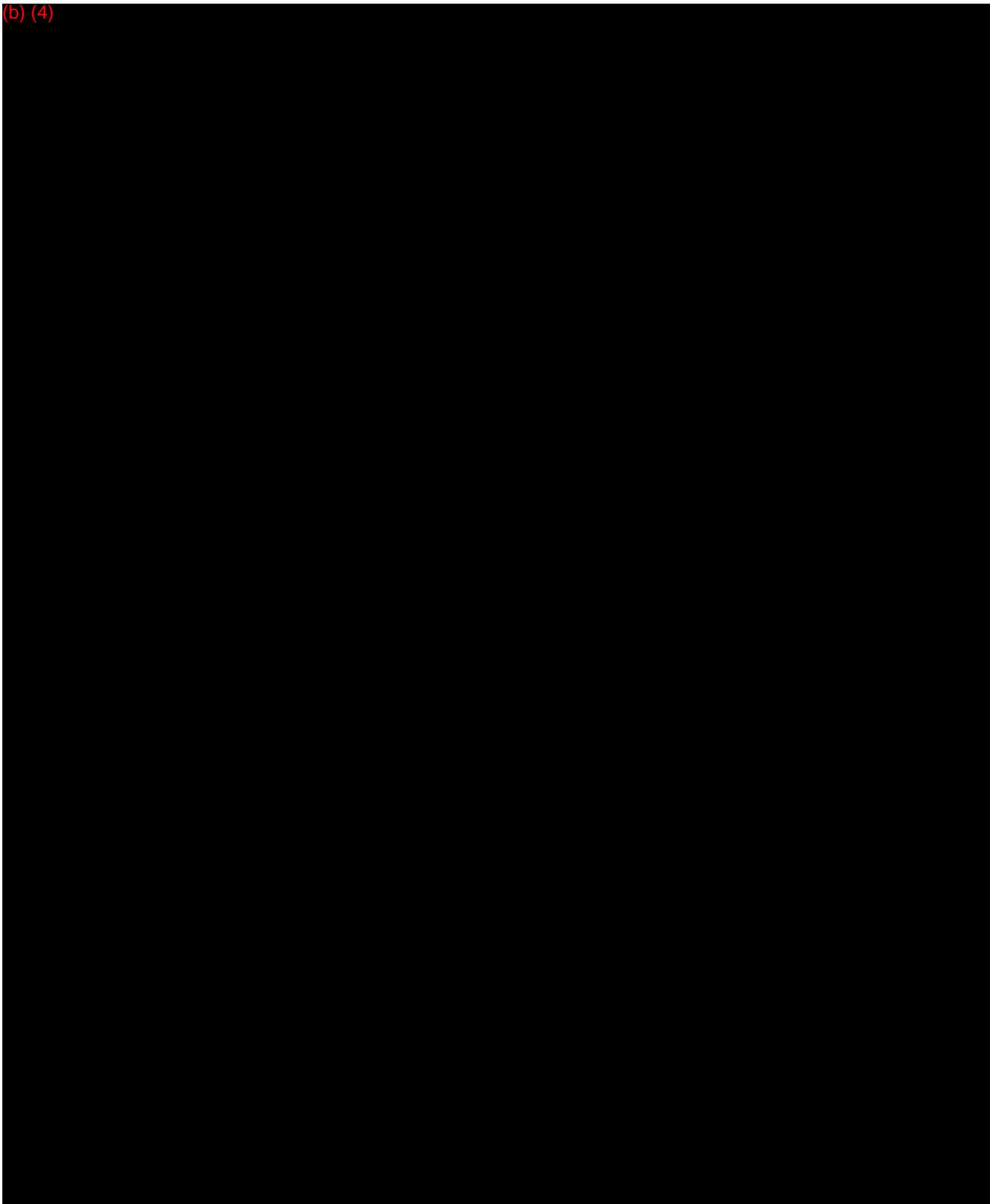
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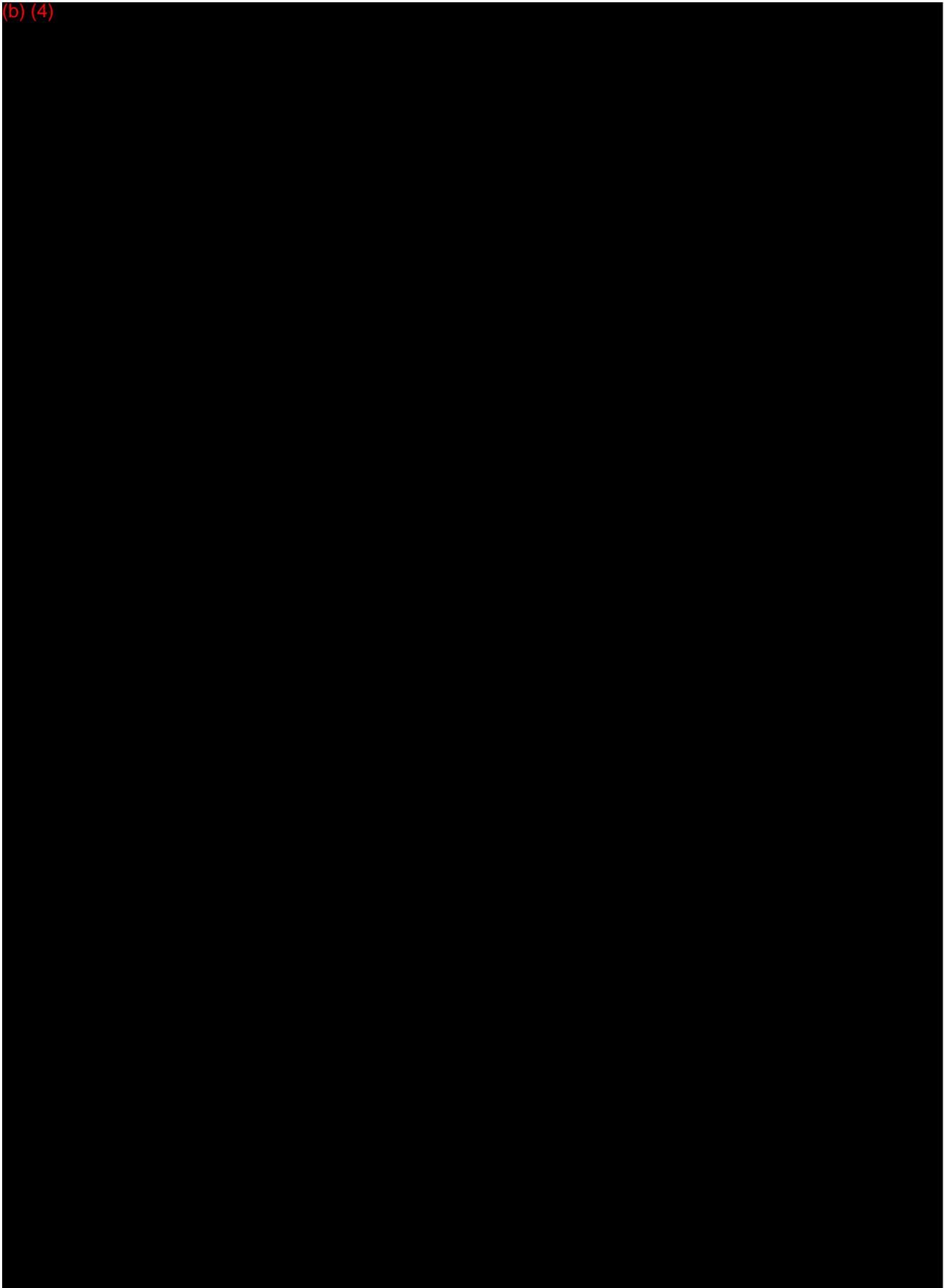
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(b) (4)



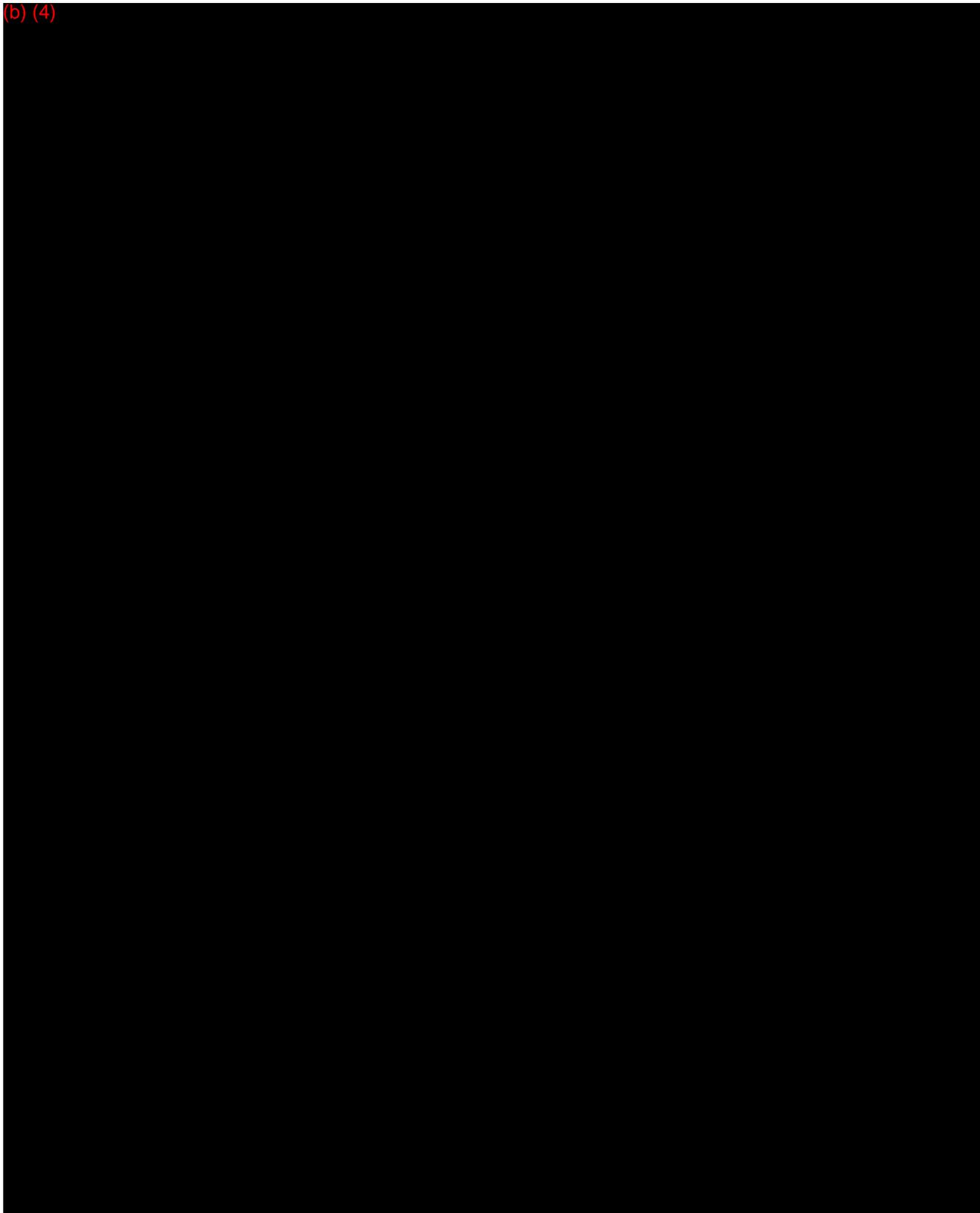
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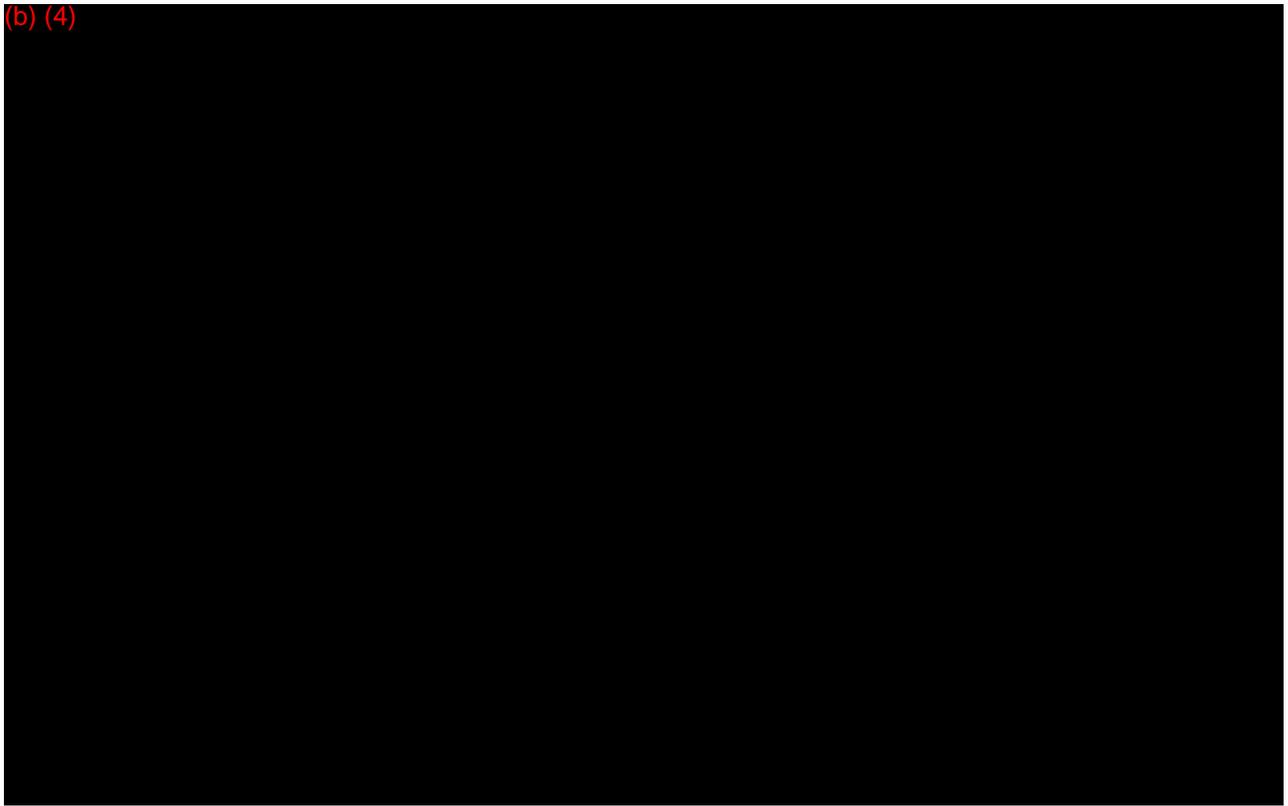
CONFIDENTIAL

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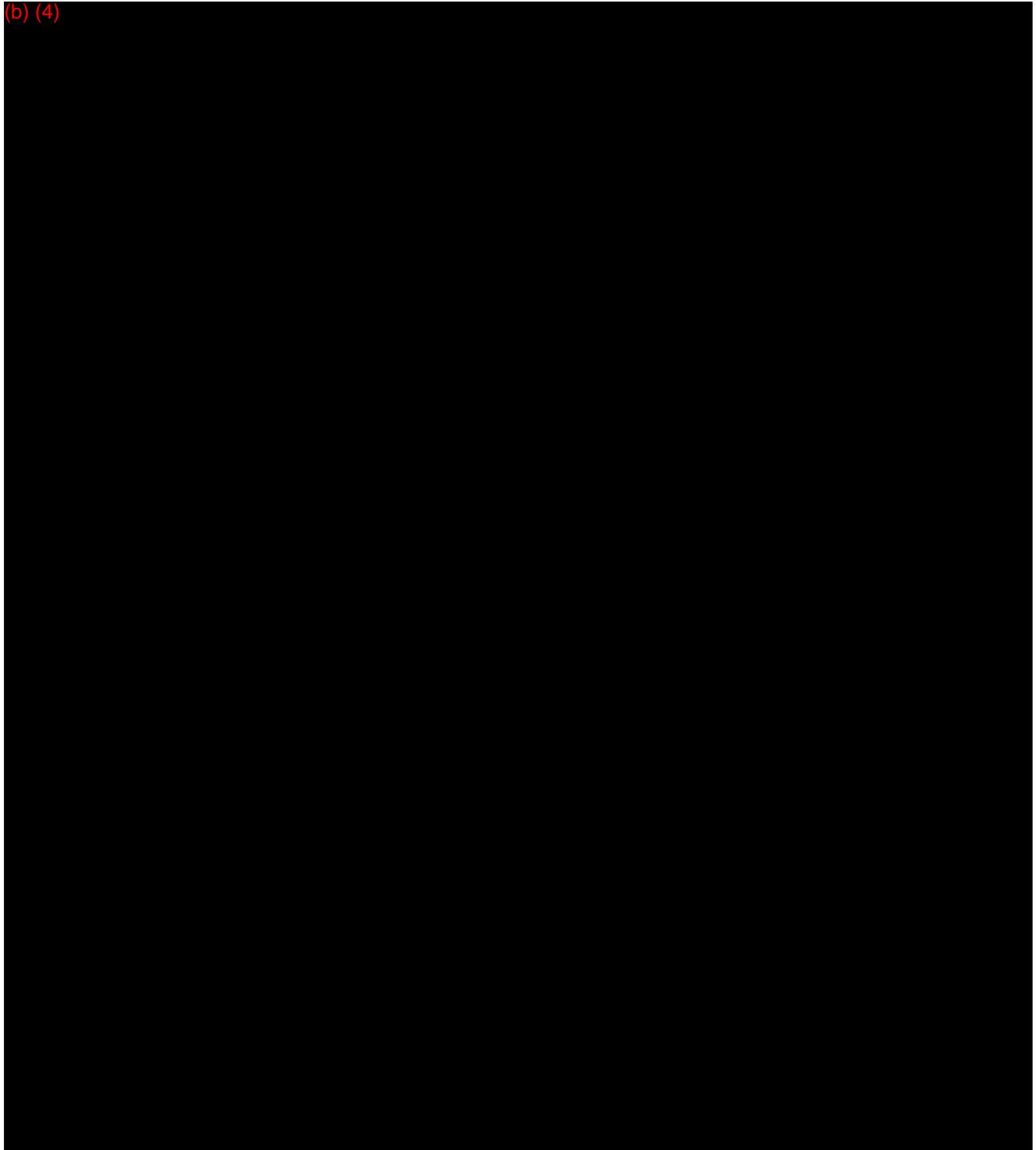
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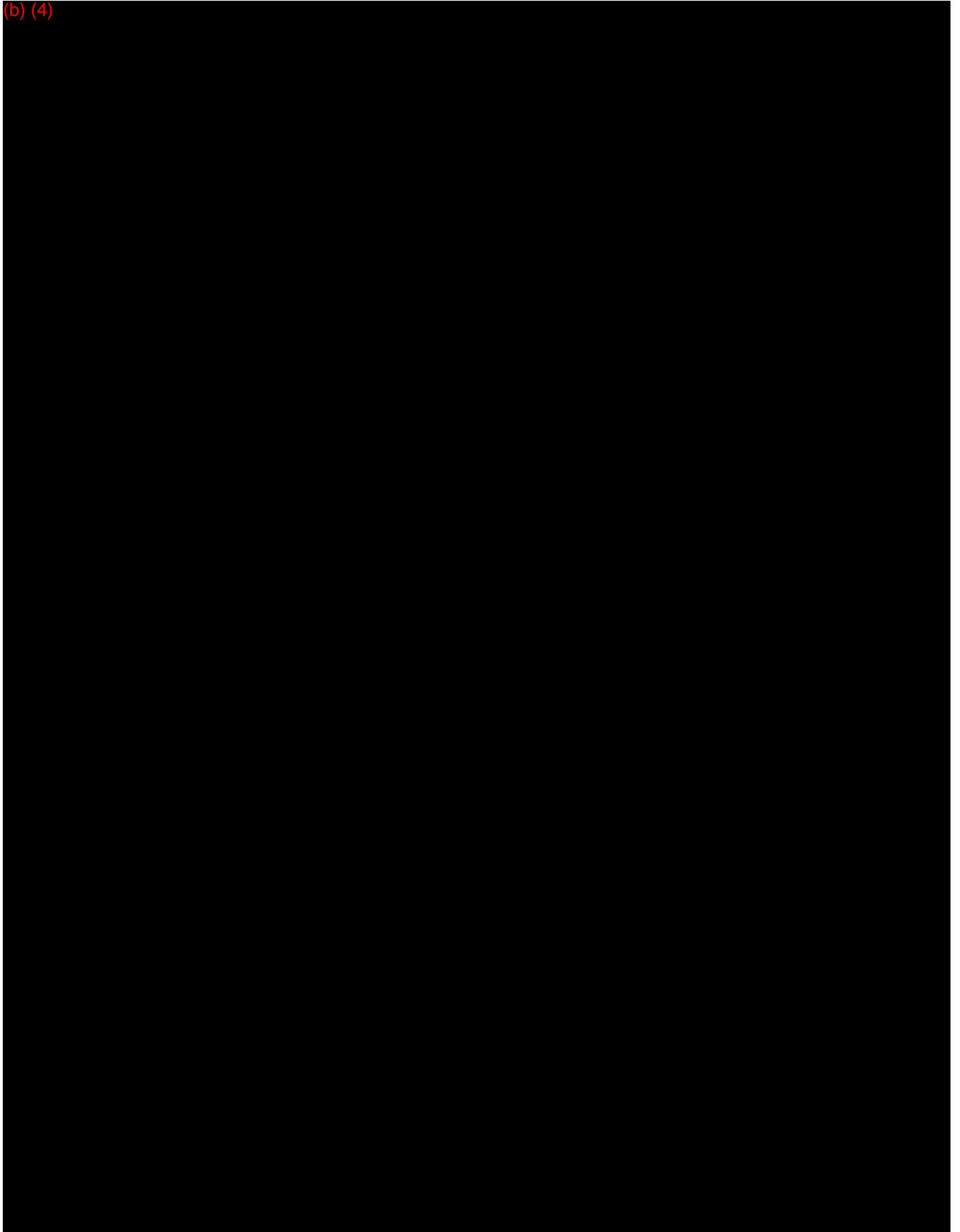
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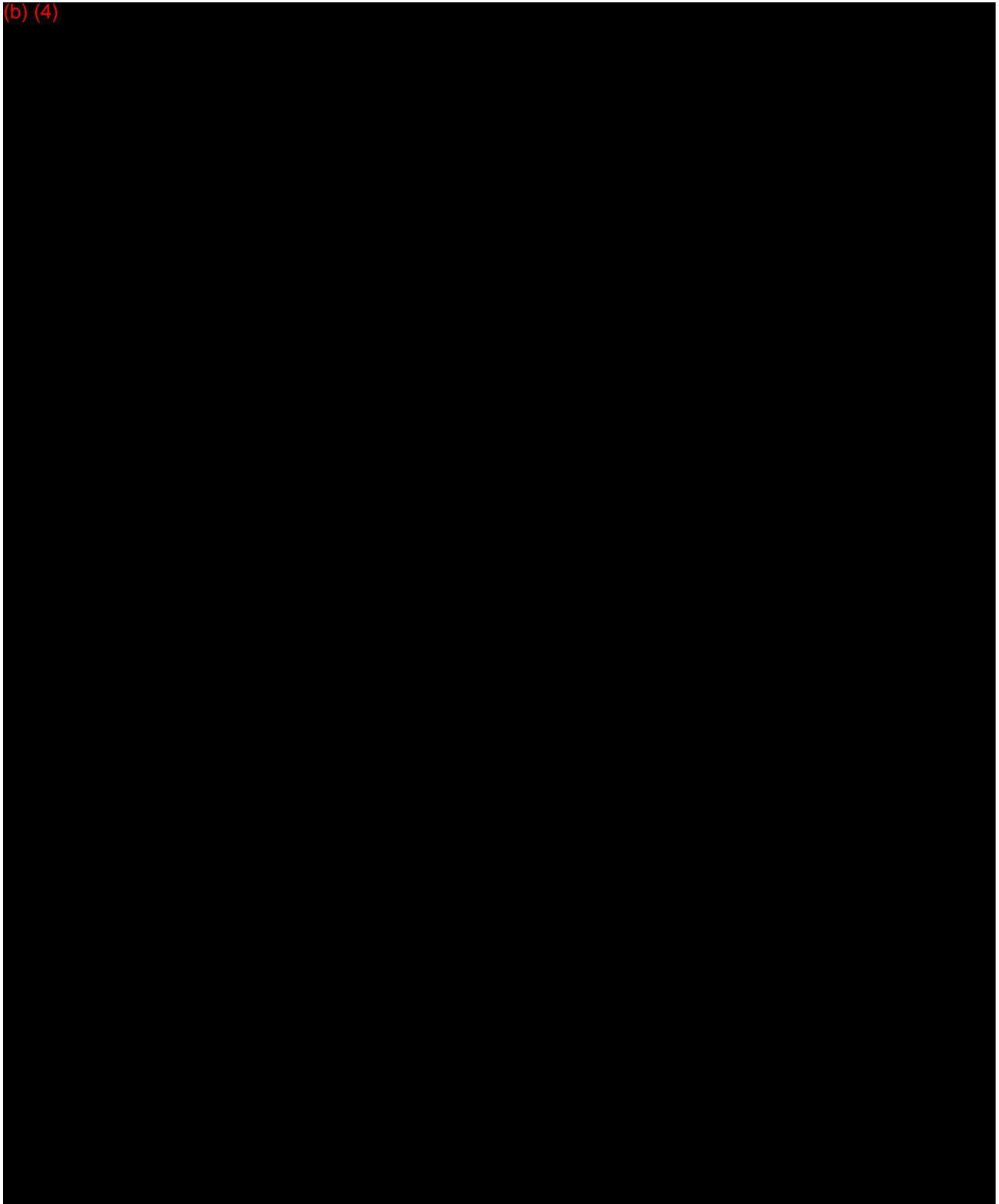
(b) (4)



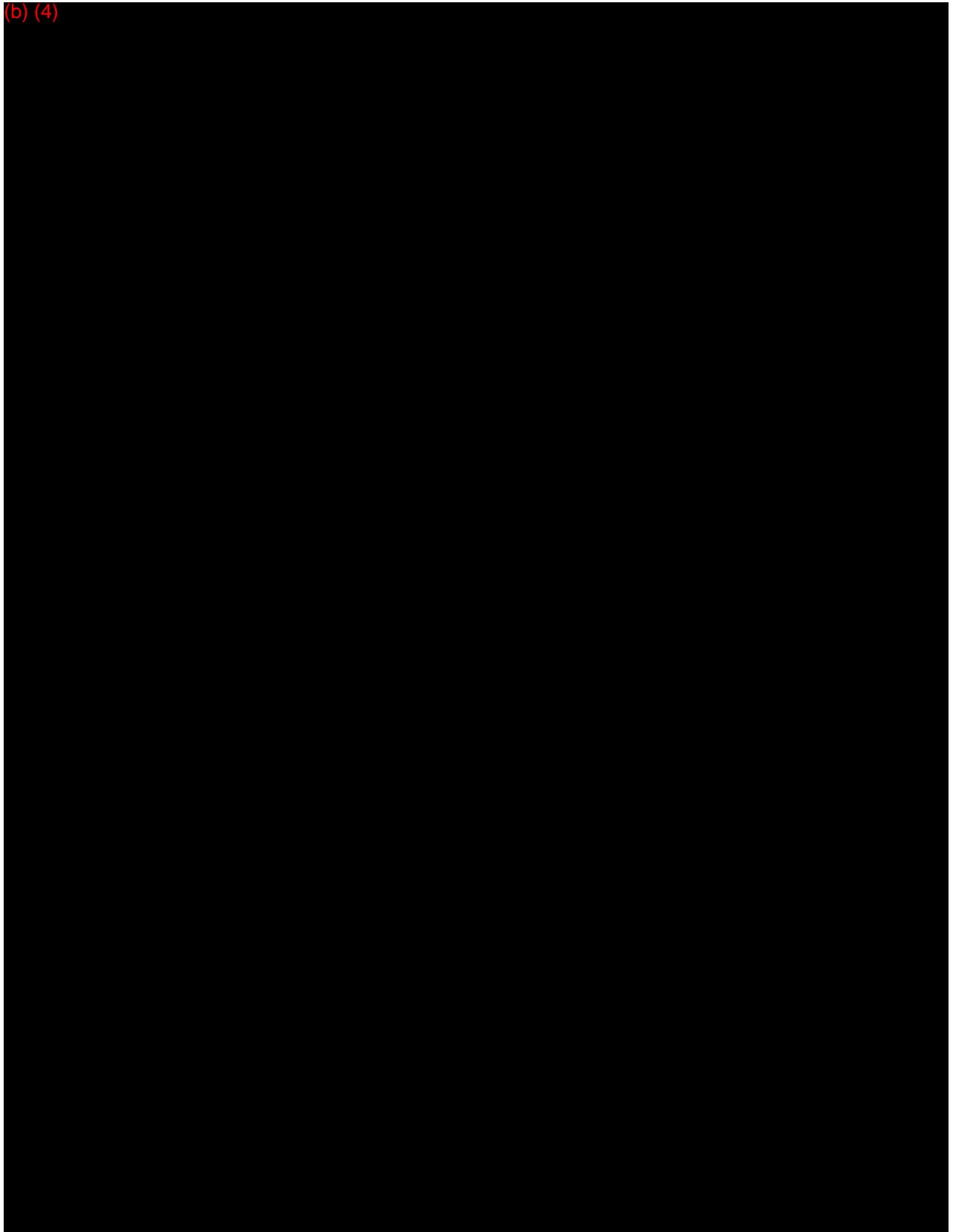
(b) (4)



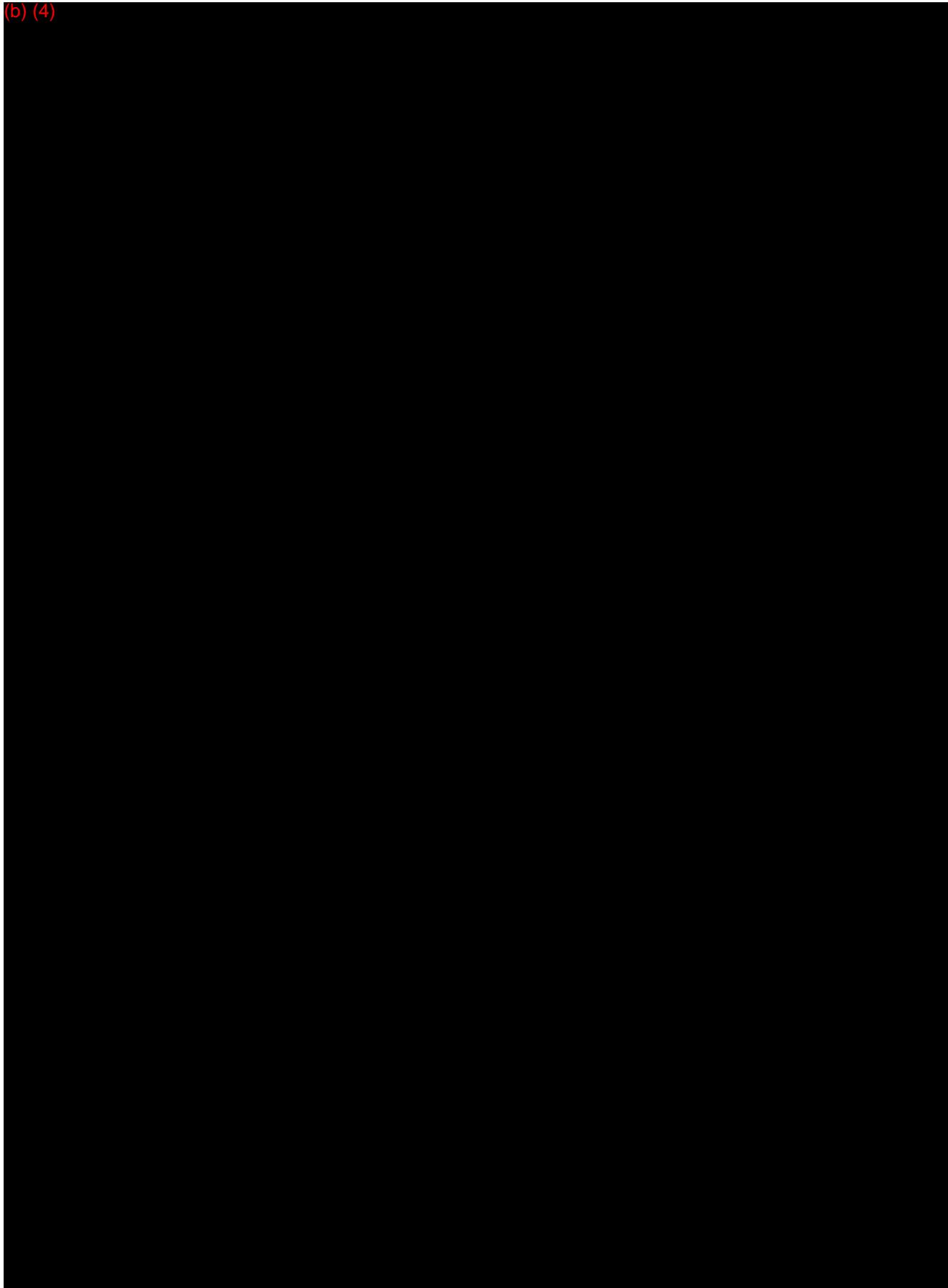
(b) (4)



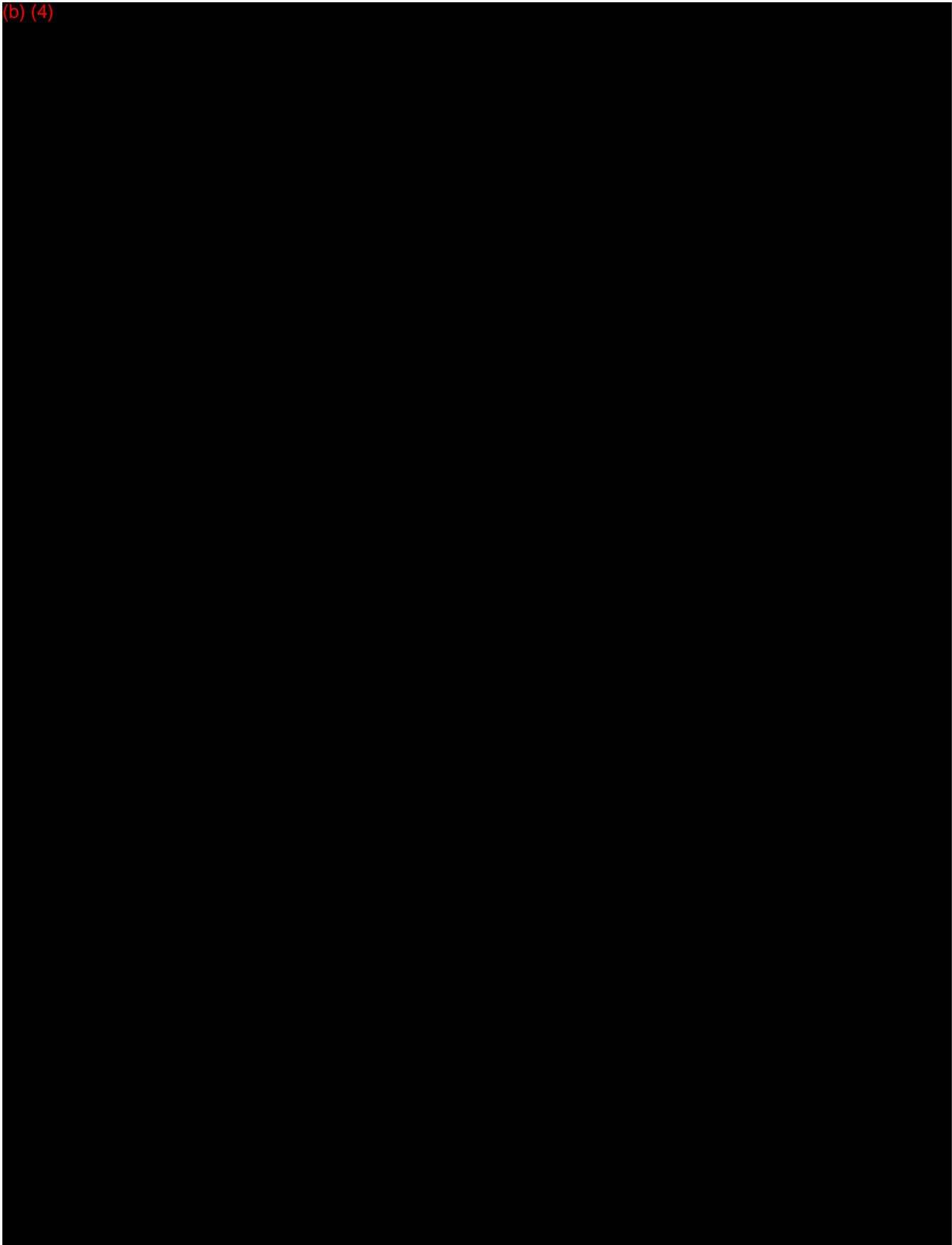
(b) (4)



(b) (4)



(b) (4)



(b) (4)



Section 19: Performance Testing – Animal

Animal Performance Data was not required to support substantial equivalence. The device functionality was deemed substantially equivalent to the predicate device via bench testing, provided in Section 18. There has been no change to the clip material or design. There has been no change to the device as it relates to patient interface.

Section 20: Performance Testing – Clinical

This section is not applicable. Clinical data was not required to show equivalency. support substantial equivalence. Clinical data is not necessary to evaluate safety and effectiveness for purposes of determining substantial equivalence.

Section 21: Other

This section contains completed copies of FDA Form 3654 for the standards referenced in this submission. The referenced standards include the following:

AAMI/ANSI/ISO 10993-1:2003 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing.

AAMI/ANSI/ISO 11137-1: 2006 Sterilization of Health Care Products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

AAMI/ANSI/ISO 11137-2: 2006 Sterilization of Health Care Products - Radiation - Part 2: Establishing the sterilization dose

AAMI/ANS/ISO 11137-3:2006 Sterilization of Health Care Products - Radiation - Part 3: Guidance on Dosimetric Aspects.

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI/ISO 10993-1:2003 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing 2003

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 2-98

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: FDA General Program Memorandum #G 95-1: Use of International Standard ISO 10993

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

AAMI/ANSI/ISO 10993-1:2003 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing 2003

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

1	Scope	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

2	Terms and Definitions	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

3	General principles applying to biological evaluation of medical devices	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
---	---	--

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Rockville, MD 20850

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE AAMI/ANSI/ISO 10993-1:2003 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing 2003		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 4	SECTION TITLE Categorization of medical devices	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * See attached page titled "Attachement to FDA Form 3654, Options for selected ISO 10993-1		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 5	SECTION TITLE Testing	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * See attached page titled "Attachement to FDA Form 3654, Options for selected ISO 10993-1		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 6	SECTION TITLE Selection of biological evaluation tests	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * See attached page titled "Attachement to FDA Form 3654, Options for selected ISO 10993-1		
DESCRIPTION		
JUSTIFICATION		
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE AAMI/ANSI/ISO 10993-1:2003 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing 2003		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 7	SECTION TITLE Assurance of test methods	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * See attached page titled "Attachement to FDA Form 3654, Options for selected ISO 10993-1		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
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Department of Health and Human Services
Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI/ISO 11137-1:2006 Sterilization of Health Care Products - Radiation Part 1

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 14-297

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE AAMI/ANSI/ISO 11137-1:2006 Sterilization of Health Care Products - Radiation Part 1		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 1	SECTION TITLE Scope	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED †		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 2	SECTION TITLE Normative References	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED †		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 3	SECTION TITLE Terms and Definitions	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED †		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>† Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE AAMI/ANSI/ISO 11137-1:2006 Sterilization of Health Care Products - Radiation Part 1		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 4	SECTION TITLE Quality Management System Benefits	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED †		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 5	SECTION TITLE Sterilizing Agent Characterization	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED †		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 6	SECTION TITLE Process and Equipment Characterization	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED † 6.2 Process and equipment characterization was done for Gamma Irradiators.		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>† Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE AAMI/ANSI/ISO 11137-1:2006 Sterilization of Health Care Products - Radiation Part 1		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 7	SECTION TITLE Product Definition	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Option - Validation of a product family		
DESCRIPTION The sterilization dose was established for the product family.		
JUSTIFICATION		
SECTION NUMBER 8	SECTION TITLE Process Definition	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Option - Substantiation of 25kyGy as a sterilization dose.		
DESCRIPTION The sterilization dose of 25kyGy was selected and substantiated.		
JUSTIFICATION		
SECTION NUMBER 9	SECTION TITLE Validation	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>† Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE AAMI/ANSI/ISO 11137-1:2006 Sterilization of Health Care Products - Radiation Part 1		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 10	SECTION TITLE Routine Monitoring and Control	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Option - Gamma irradiator controls		
DESCRIPTION Requirements implemented for gamma irradiator controls		
JUSTIFICATION		
SECTION NUMBER 11	SECTION TITLE Product Release from Sterilization	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 12	SECTION TITLE Maintaining Process Effectiveness	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI/ISO 11137-2:2006 Sterilization of Health Care Products - Radiation Part 2

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 14-225

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
AAMI/ANSI/ISO 11137-2:2006 Sterilization of Health Care Products - Radiation Part 2

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Normative References	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Abbreviations	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE AAMI/ANSI/ISO 11137-2:2006 Sterilization of Health Care Products - Radiation Part 2		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 4	SECTION TITLE Definition and maintenance of product families	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * 		
DESCRIPTION 		
JUSTIFICATION 		
SECTION NUMBER 5	SECTION TITLE Selection and Testing of Product for Establishing and Verifying Ster, Dose	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * 		
DESCRIPTION 		
JUSTIFICATION 		
SECTION NUMBER 6	SECTION TITLE Methods of Dose Establishment	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Option selected was VDmax25.		
DESCRIPTION 		
JUSTIFICATION 		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement		
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE AAMI/ANSI/ISO 11137-2:2006 Sterilization of Health Care Products - Radiation Part 2		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 7	SECTION TITLE Method 1: Dose Setting Using Bioburden Information	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * 		
DESCRIPTION 		
JUSTIFICATION 		
SECTION NUMBER 8	SECTION TITLE Method 2: Dose Setting Using Fraction Positive Information	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * 		
DESCRIPTION 		
JUSTIFICATION 		
SECTION NUMBER 9	SECTION TITLE Method VDmax: Substantiation of 25 KGy or 15 KGy as sterilization dose	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Option selected was VDmax 25.		
DESCRIPTION Substantiation of 25 KGy as sterilization dose.		
JUSTIFICATION 		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE AAMI/ANSI/ISO 11137-2:2006 Sterilization of Health Care Products - Radiation Part 2		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 10	SECTION TITLE Auditing Sterilization Dose	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 11	SECTION TITLE Worked Examples	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI/ANSI/ISO 11137-3:2006 Sterilization of Health Care Products - Radiation Part 3

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 14-298

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE AAMI/ANSI/ISO 11137-3:2006 Sterilization of Health Care Products - Radiation Part 3		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 1	SECTION TITLE Scope	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * 		
DESCRIPTION 		
JUSTIFICATION 		
SECTION NUMBER 2	SECTION TITLE Normative References	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * 		
DESCRIPTION 		
JUSTIFICATION 		
SECTION NUMBER 3	SECTION TITLE Terms and Definitions	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Option selected was VDmax25.		
DESCRIPTION Substantiation of 25 KGy as sterilization dose.		
JUSTIFICATION 		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement		
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE AAMI/ANSI/ISO 11137-3:2006 Sterilization of Health Care Products - Radiation Part 3		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 4	SECTION TITLE Measurement of Dose	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 5	SECTION TITLE Selection and Calibration of Dosimetry Systems	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 6	SECTION TITLE Establishing the Maximum Acceptable Dose	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE AAMI/ANSI/ISO 11137-3:2006 Sterilization of Health Care Products - Radiation Part 3		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 7	SECTION TITLE Establishing the Sterilization Dose	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED [♦]		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 8	SECTION TITLE Installation Qualification	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED [♦]		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 9	SECTION TITLE Operational Qualification	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED [♦] Option selected was VDmax 25.		
DESCRIPTION Substantiation of 25 KGy as sterilization dose.		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>[♦] Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE AAMI/ANSI/ISO 11137-3:2006 Sterilization of Health Care Products - Radiation Part 3		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 10	SECTION TITLE Performance Qualification	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * Performance qualification performed for Gamma Irradiator.		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 11	SECTION TITLE Routine Monitoring and Control	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
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**Attachment to FDA Form 3654
Options Selected for ISO 10993-1**

Options Selected from Clause 4 of ISO 10993-1 for Form 3654, Section 4

For Surface Contacting Device the following options were selected: 4.2.2, Surface Contacting Devices (a) Skin Limited Contact (<24 hours); 4.2.3 External Communicating Devices (b) Tissue/bone/dentin Limited Contact (<24 hours); 4.2.4 Implant Devices (a) Tissue Bone Permanent Contact (>30 days).

Options Selected from Clause 5 of ISO 10993-1 for Form 3654, Section 5

For Surface contacting Device – Skin (Limited <24 hours) the following options were selected 5.2.2, Cytotoxicity utilized ISO 10993-5; 5.2.3. Sensitization utilized ISO 10993-10; 5.2.5 Intracutaneous Reactivity utilized ISO 10993-10.

For external communicating devices – Tissue/Bone/Dentin (Limited <24 hours) the following options were selected: 5.2.2, Cytotoxicity utilized ISO 10993-5; 5.2.3. Sensitization utilized ISO 10993-10; 5.2.5 Intracutaneous Reactivity utilized ISO 10993-10.

For Implant Devices – Tissue/Bone (Permanent Contact >30 days) the following options were selected: 5.2.2. Cytotoxicity utilized ISO 10993-5; 5.2.3. Sensitization utilized ISO 10993-10; 5.2.5 Intracutaneous Reactivity utilized ISO 10993-10; 5.2.6 Systemic Toxicity (Acute) utilized ISO 10993-11; 5.2.7 Subacute and Subchronic Toxicity utilized ISO 10993-11; 5.2.8 Genotoxicity utilized ISO 10993-3; 5.2.9 Implantation utilized ISO 10993-6.

Options Selected from Clause 6 of ISO 10993-1 All the test in Table 1 that were recommended for this device have been conducted as discussed in Section 5 of FDA Form 3654. The following tests from Table 2 were conducted for implant devices tissue/bone, permanent contact >30 days: Chronic Toxicity (per ISO 10993-11) and Carcinogenicity (per ISO 10993-3).

Section 22: FDA Form 3674

This section does not apply; this 510(k) submission does not reference any clinical trial. Per the FDA guidance document “Guidance for Sponsors, Industry, Researchers, Investigators, and Food and Drug Administration Staff - Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”, FDA Form 3674 is not required for 510(k)s that do not refer to, relate to, or include information on or from a clinical trial.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER Ethicon Endo-Surgery Inc. c/o Asifa Vonhof	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES Mar 10, 2011
3. ADDRESS (Number, Street, State, and ZIP Code) 4545 Creek Road Cincinnati, OH, 45242	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) (513) 337-1546 (Fax) (513) 337-2802

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Ligamax 5

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
 IND NDA ANDA BLA PMA HDE 510(k) PDP Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

NCT Number(s): _____

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Emily Krueczkamp (Title) Regulatory Affairs Associate
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) 4545 Creek Road Cincinnati, OH, 45242	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) (513) 337-1546 (Fax) (513) 337-2802
15. DATE OF CERTIFICATION 3/10/2011	

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

- 1. Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
- 2. Date** - This is the date of the application/submission which the certification accompanies.
- 3. & 4.** - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
- 5. Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
- 6. Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
- 7. IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
- 8. Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
- 9. Certification** - This section contains three different check-off boxes.
Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.
Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.
Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
- 10. National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/submission.
- 11. Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
- 12. Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
- 13. & 14.** - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
- 15.** Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-250)
5600 Fishers Lane
Rockville, MD 20857

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



COVER SHEET MEMORANDUM

From: Reviewer Name Della Hammond
Subject: 510(k) Number K110699
To: The Record

Please list CTS decision code SE

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
510(k) Summary /510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III? If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		✓	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)	
Nanotechnology	
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.

Regulation Number	Class*	Product Code
818.4150	II	GDW

Additional Product Codes: ^{(*If unclassified, see 510(k) Staff)} GAG

Review: David Kirne (Branch Chief) PRSB (Branch Code) 3/25/2011 (Date)

Final Review: ALB (Division Director) for rxn 3/25/11 (Date)

S

REVISED: 3/14/95

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

K 110699

Reviewer: D. B. Hammond

Division/Branch: DSORD/PR SB

Device Name: LIGAMAX 5

Product To Which Compared (510(K) Number If Known): K050344

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

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:
This is a device.
2. Explain why not subject to 510(k):
This device is subject to 510(k) process.
3. How does the new indication differ from the predicate device's indication:
Indication is identical to the predicate.
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
No new technological characteristics other than enhancements to improve ^{usage} of the device.
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
Descriptive characteristics are 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 demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):	YES	NO
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see <u>H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC</u>)		✓
2. Is the device exempt from 510(k) by regulation (Please see <u>http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC</u> or subject to enforcement discretion (No regulation - See 510(k) Staff)?		✓
3. Does this device type require a PMA by regulation? (Please see management.)		✓
Questions 4-8 are intended to help you start your review:	YES	NO
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, <u>http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%20%202007.doc</u>)		✓
5. a. Did the firm request expedited review? (See management.) b. Was expedited review granted? (See <i>Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions</i> , <u>http://www.fda.gov/cdrh/mdufma/guidance/108.html</u>)		✓
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:	✓
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:	✓
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see <i>Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission</i> <u>http://www.fda.gov/cdrh/mdufma/guidance/1215.html</u>)		✓

Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

**Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s**
<http://www.fda.gov/cdrh/ode/guidance/1567.html>

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html	✓		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Voluntary Cover Sheet www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf	✓		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/cdrh/ode/guidance/1567.html	✓		
Indications for Use Statement	Device Advice "Content of a 510(k)" Section D www.fda.gov/cdrh/devadvice/314312.html#link_6	✓		
510(k) Summary or 510(k) Statement	Device Advice "Content of a 510(k)" Section E www.fda.gov/cdrh/devadvice/314312.html#link_7	✓		
Truthful and Accuracy Statement	Device Advice "Content of a 510(k)" Section G www.fda.gov/cdrh/devadvice/314312.html#link_9	✓		
Class III Summary and Certification	Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html			
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html			
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations www.fda.gov/cdrh/ode/guidance/1131.html . FDA Standards program www.fda.gov/cdrh/stdsprog.html . Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard www.fda.gov/cdrh/ode/regrecstand.html			

R/ 30/07

Title	Related Information	Present	Inadequate	N/A
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓		
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), www.fda.gov/cdrh/k863.html	✓		
Proposed Labeling	Device Advice "Content of a 510(k)" Section H www.fda.gov/cdrh/devadvice/314312.html#ink_10	✓		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) www.fda.gov/cdrh/ode/guidance/361.html For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices www.fda.gov/cdrh/ode/guidance/1216.html	✓		
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" www.fda.gov/cdrh/g951.html	✓		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices www.fda.gov/cdrh/ode/software.html			
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program www.fda.gov/cdrh/emc See also IEC 60601-1- 2 Medical Electrical Equipment – Part 1: General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests (Second Edition, 2001)			
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓		
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf			

Title	Related Information	Present	Inadequate	N/A
FORM FDA 3654, <i>Standards Data Report for 510(k)s - http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</i>	Standards Data Report Form – Form 3654 1: No standard used - No Standards Form Required 2: Declaration of Conformity – Yes Standards Form Required 3: Standard but no declaration – Yes Standards Form Required	✓		
Kit Certification	Device Advice http://www.fda.gov/cdrh/ode/odecl874.html			

Last Updated: 9/3/08 – Brandi Stuart



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

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

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

K110699

Date: March 17, 2011

To: The Record

From: Della Hammond, MPH, Microbiologist, PRSB, DGRND 
510(k) Holder: Ethicon Endo-Surgery, LLC

Office: ODE

Division: DGRND

Device Name: Ethicon Endosurgery Ligamax™ 5

Contact: Emily Kruetzkamp

Address: 4545 Creek Road, Cincinnati, OHIO 45242

Email: ekruetzka@its.jnj.com

Phone: 513-337-1546

Fax: 513-337-2729

***SE**

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the Ethicon Endosurgery Ligamax™ 5 into interstate commerce. The purpose of this 510(k) is to notify FDA of design changes and incremental enhancements made to the Ethicon Endo-Surgery Ligamax™ 5 Endoscopic Multiple Clip Applier.

The Ethicon Endosurgery Ligamax™ 5 is sterile, single patient use 5mm endoscopic multiple clip applier 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.

The firm is claiming substantial equivalence to the LIGACLIP® 5 M/L Endoscopic Multiple Clip Applier, K050344. Comparison Tables are provided beginning on page 41 of the submission.

The subject device has many of the same technological characteristics as the predicate device, such as the handle design with an actuation trigger, rotation knob, shaft with an outer diameter of 5.5 cm and a length of 33 cm, and an end effector portion with jaws for forming ligating clips. Additionally, the feed-form sequence, ligating clips, and indication for the subject device have not changed. The main difference noted by the firm are jar aperture, line of demarcation and the amount of force used to fire through the tactile "no-clip lockout" indicator. Therefore, based on similarities in design, intended use, and performance, I find the proposed device to be substantially equivalent to the predicate.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		

JS

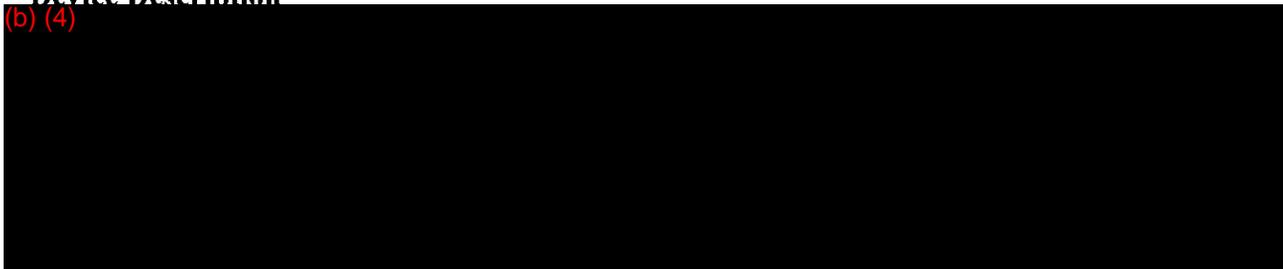
	Yes	No	N/A
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form			

III. Device Description

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

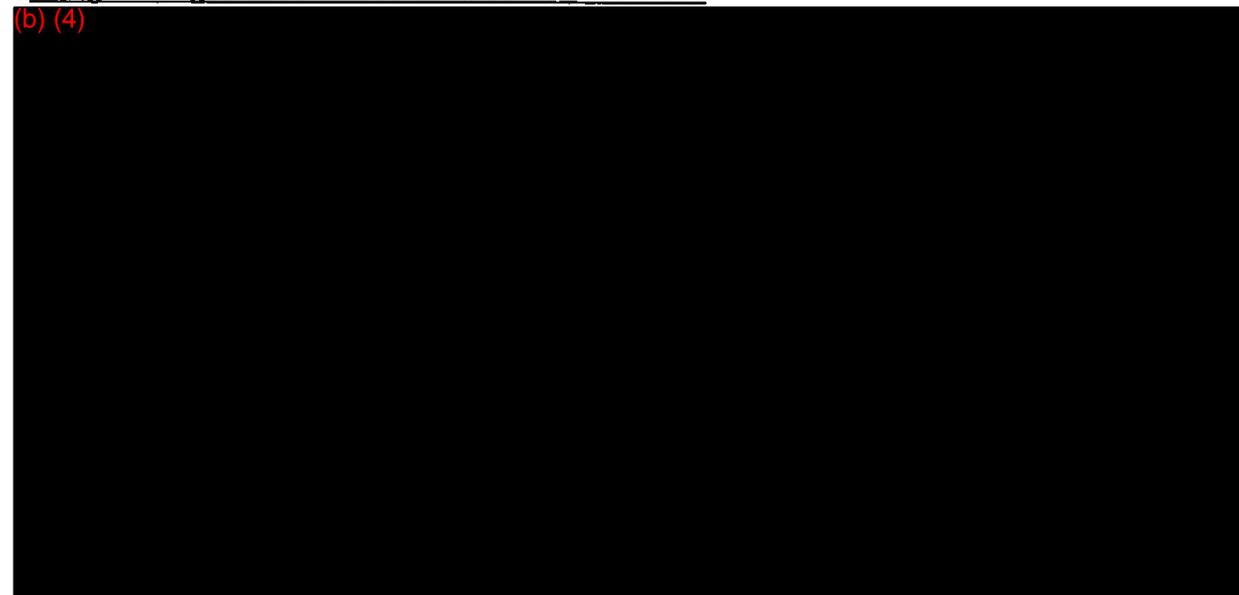
Device Description

(b) (4)



Design changes described in this submission include:

(b) (4)



IV. Indications for Use

The LIGACLIP®P 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.

14

V. Predicate Device Comparison

The firm is claiming substantial equivalence to the LIGACLIP® 5 M/L Endoscopic Multiple Clip Applier, K050344. The subject device has many of the same technological characteristics as the predicate device, such as the handle design with an actuation trigger, rotation knob, shaft with an outer diameter of 5.5 cm and a length of 33 cm, and an end effector portion with jaws for forming ligating clips. Additionally, the feed-form sequence, ligating clips, and indication for the subject device have not changed.

The firm has provided a Comparison Table to provide a detailed side-by-side comparison of the subject and predicate devices with respect to technology and device performance. See page 42, Section 12 for a side-by-side comparison of performance specifications for the subject device and predicate device. The main difference noted by the firm are jar aperture, line of demarcation and the amount of force used to fire through the tactile "no-clip lockout" indicator.

In review of the predicate, the proposed device is substantially equivalent with regard to function, materials, indications, sterilization, and labeling. Therefore, based on similarities in design, intended use, and performance, I find the proposed device to be substantially equivalent to the predicate.

VI. Labeling Section 13

Proposed labels and labeling are provided as Section 13 of the submission. The firm has provided proposed packaging labels and instructions for use. The labeling is acceptable. The draft labeling includes the indications statement, directions for use and removal, ingredients, expiration dating, storage information, and the following contraindications, warnings and precautions:

Instructions For Use

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

- 1 Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
- 2 Remove protective cap from the jaws of the instrument.
- 3 Insert the clip applier through an appropriately-sized trocar. The empty jaws will passively collapse as they are inserted through a 5 nun trocar (Illustration 2) and reopen when completely through the trocar. (Illustration 3)
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 before inserting the device through the trocar.
- 4 Prior to loading a clip in the jaws and firing the instrument: ensure that the jaws are fully open by verifying that the line of demarcation between the jaws and the instrument shaft is past the distal end of the trocar cannula. (Illustration 3)
- 5 Prior to positioning the jaws around the tubular structure or vessel, load a clip into the jaws by partially squeezing the trigger in a smooth continuous motion for approximately one-third of the total firing stroke. (Illustration 4)
Caution: Inspect the jaw tips to ensure the clip is fully advanced in the jaws. (Illustration 4)
- 6 Position the jaws with the preloaded clip completely around the tubular structure or vessel to be ligated. The structure to be ligated should be positioned against the apex of the clip. (Illustration 5)
Note: The shaft can be rotated 360 degrees to facilitate visualization and accurate placement.

Caution: Ensure that the clip is the correct size for the vessel or tubular structure being ligated. If the vessel or tubular structure is too large for the clip, remove the device and use an appropriately sized - ligation device.

Caution: Do not excessively twist or torque the instrument jaws when positioning or firing the

15

- instrument on a tubular structure or vessel. Excessive twisting or torquing may result in clip malformation. (Illustration 6)
- 7 Complete the firing cycle by squeezing the trigger until it stops against the handle to completely form the clip on the targeted structure or vessel. (Illustration 7)
Caution: The trigger must be fully squeezed against the handle to ensure complete clip formation.
S After firing, fully release the trigger.
Note: A clip will not be loaded in the jaws until the trigger is squeezed again.
 - 9 Check to ensure that each clip has been securely placed around the tissue being ligated.
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 the 13th clip is fired, an orange bar will begin to appear in the indicator window on top of the device handle. (Illustration 8) The orange bar fills the indicator window when the final clip is fired.
Note: The instrument contains a last clip lockout feature designed to increase the force required to close the trigger, thereby reducing the possibility that the empty jaws will be closed on a structure or vessel. Do not attempt to fire through the lockout. If force applied to trigger exceeds the last clip lockout, the jaws may remain closed. If the jaws do not open when the trigger is released, pull the trigger outward to re-open the jaws. Do not re-fire the instrument.
 - 12 To remove the instrument, ensure there is no clip remaining in the jaws and withdraw the instrument from the trocar.
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.

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 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 in the jaws, fully squeeze the trigger against the handle, then fully release the trigger to release the clip from the jaws before inserting the device through the trocar.

Inspect the jaw tips to ensure the clip is fully advanced in the jaws of the instrument:

Ensure that each clip is securely and completely positioned around the tissue being ligated before completion of firing cycle.

Do not excessively twist or torque the instrument jaws when positioning or firing the instrument on 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.

Do not attempt to fire through the last clip lockout. Closing the instrument's jaws over a vessel or structure without a clip could result in damage to the vessel or structure.

Do not attempt to remove closed jaws from the structure or vessel. This could result in damage to the structure or vessel. Pull the trigger outward to re-open the jaws.

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.

Firing the instrument over another clip or instrument can also damage a properly deployed clip, disrupt related vessels and structures, and damage the instrument.

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.

Dispose of all opened instruments whether used or unused.

This device is packaged and sterilized 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 that 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.

VII. Sterilization/Shelf Life/Reuse Section 14

The subject Ligamax 5 will be supplied sterile for single patient use and is not intended to be reused or resterilized.

Terminal Sterilization Method: Cobalt 60 irradiation

SAL: (b)

Dose: (b) (4)

Standard: (b) (4)

Shelf Life: 5 year shelf life

The firm reports there have been no changes to the shelf life of Ligamax 5 from the predicate device. The shelf life of the product is five years.

Packaging

The subject Ligamax™ 5 is packaged in a clear (b) (4) blister package with a heat-sealed preprinted Tyvek lid. Three sealed (b) (4) blisters are placed in an (b) sales unit carton. Four of the (b) sales unit cartons are placed in a corrugated shipper, same as the predicate.

VIII. Biocompatibility Section 15

The firm reports there have been no new patient-contacting materials introduced to the Ligamax™ 5. The firm reports that the subject device is manufactured from materials that have been evaluated for biocompatibility for their intended patient contact profile according to ISO 10993-1 and/or USP standards. The firm notes that the Feeder Shoe component was initially categorized as a Surface Component with less than a 24 hour contact category; thus, upon further evaluation, was reclassified and has been tested to a more rigorous classification of Externally Communicating Component with Tissue or Bone Contact of Less Than 24 hours.

The firm reports the materials used in the proposed Ligamax™ 5 was evaluated based on ISO 10993-1:2003 "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".

IX. Software
N/A

Version:	n/a	
Level of Concern:		
	Yes	No
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety
N/A

XI. Performance Testing – Bench (Section 18)

The following bench performance testing was completed to demonstrate substantial equivalence of the subject device to the predicate device. Details concerning the test methods, acceptance criteria, results and discussion are contained in Section 18 Performance Testing - Bench.

Device performance was assessed against the design requirement for each of the following functions:

- (b) (4)
-
-
-
-
-
-
-
-
-
-

See Section 18 for protocols and tests results.

XII. Performance Testing – Animal
NA

XIII. Performance Testing – Clinical

N/A

XIV. Substantial Equivalence Discussion

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

Note: See

http://erom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

When developing deficiencies please consider the following "Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA" (<http://www.fda.gov/cdrh/modact/guidance/1195.html>) and "A Suggested Approach to Resolving Least Burdensome Issues" (<http://www.fda.gov/cdrh/modact/leastburdensome.html>).

XVI. Contact History

XVII. Recommendation: SE, K110699

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

Regulation Number: 21 CFR § 878.4800
Regulation Name: Stapler, Surgical
Regulatory Class: I
Product Code: **GAG**

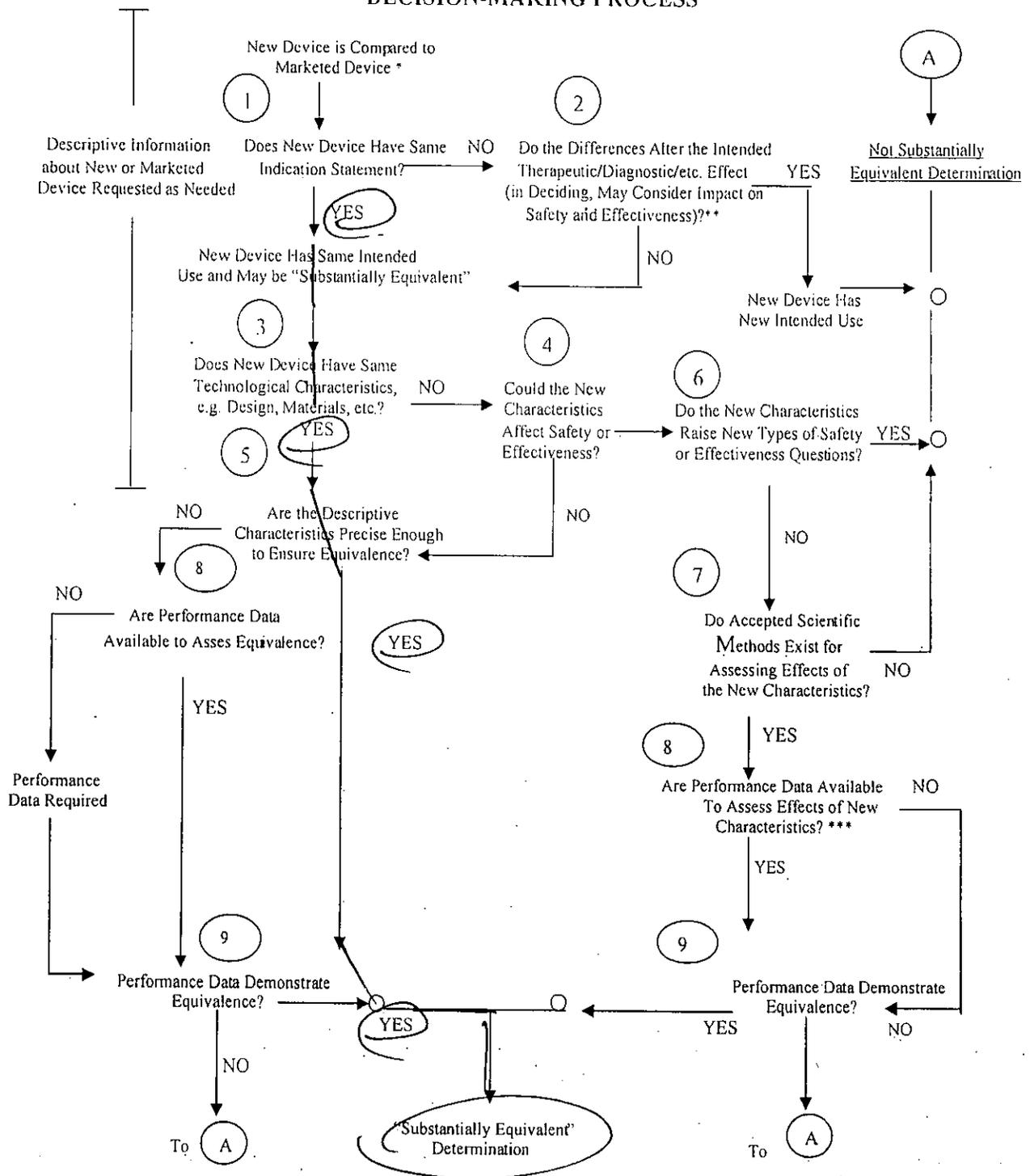
David Krane 3/25/2011 Concur
Branch Chief, Date // Do Not Concur
Division of Surgical, Orthopedic and Restorative Devices
General Surgical Devices Branch

Aj B. R. H. 3/25/11 Concur
Deputy Division Director Date // Do Not Concur
Division of Surgical, Orthopedic and Restorative Devices

Division Director Date // Concur
// Do Not Concur
Division of Surgical, Orthopedic and Restorative Devices

20

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.

6