

K151340



FDA CDRH DMC

MAY 19 2015

Received

15 May 2015

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: **Special 510(k) Premarket Notification:**
Ethicon HARMONIC® Focus Long Shears + Adaptive Tissue Technology

Dear Sir or Madam:

Pursuant to 21 CFR 807.90, Ethicon Endo-Surgery is submitting two copies of this Special 510(k) premarket notification for the Ethicon HARMONIC Focus Long Shears + Adaptive Tissue Technology. The design of the new device is based upon the predicate device HARMONIC Focus Shears + Adaptive Tissue Technology device, cleared under K133314 on 03 December 2013.

This subject device has never been submitted to the FDA before. There are no prior 510k submissions for the subject device. This is a new 510(k) submission. The subject device is not an *in vitro* diagnostic device.

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

Submission Type: Special 510(k)
Device Common Name: Instrument, Ultrasonic Surgical
Classification Name: Instrument, Ultrasonic Surgical
510(k) Submitter: Ethicon Endo-Surgery, LLC

Contact Person: Brian Godwin, RAC
Senior Regulatory Affairs Associate
Phone: (513) 337-3623
Fax: (513) 337-4366
Email: bgodwin@its.jnj.com

Confidentiality Preference: Please keep this submission confidential per 21 CFR 807.95
Classification Regulations: Unassigned
Device Class: Class II
Panel: General & Plastic Surgery
Classification Codes: LFL
Related FDA Document Numbers: K133314

1-CD
SS

Payment of the user fee has been made. A unique payment identification number (PIN) has been assigned to this submission, it is (b)(4) [REDACTED]. A copy of the Medical Device User Fee Cover Sheet has been included in Section 1 for reference.

Per the instructions contained in the guidance *Electronic Copies for Pre-Market Submissions*, an electronic copy is being provided with this submission that is an exact duplicate of the paper copy.

If there are any questions concerning this notification, please contact me at (513) 337-3623 or by email at bgodwin@its.jnj.com. If I am not available, the alternate contact person for this submission is Hortense Allison, Director, Regulatory Affairs, at (513) 337-3592.

Sincerely,



Brian Godwin, RAC
Senior Regulatory Affairs Associate

Enclosure

510(k) Premarket Notification (Special)

**Ethicon Endo-Surgery
HARMONIC[®] Focus Long Shears + Adaptive Tissue
Technology**

15 May 2015

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

CONFIDENTIAL

**Information and data contained herein are proprietary and confidential.
This information may not be divulged, published, or otherwise disclosed without
prior consent.**



Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Special 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K

Date Received by DCC:

Lead Reviewer:

Branch:

Division:

Center/Office:

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Special 510(k) Criteria

The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

	Yes	No
1) 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.	X	
Comments? Pages 5 to 10		
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).	X	
Comments? Page 14, Page 26		
3) Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).	X	
Comments? Page 27		
4) The submission includes only summary-level information (i.e., NO test reports with performance data). Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.	X	
Comments? Pages 22 to 33		

Does the submission meet all 4 criteria above?

- Yes, submission meets criteria for a Special 510(k). Continue with the remainder of this checklist below.
- No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist; convert to a Traditional using the form below and apply the Traditional checklist.

Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes No N/A Comment

A. Administrative

1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)

×

2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet ([Form 3514](#)) or 510(k) cover letter):

×

×

a) Device trade name or proprietary name

×

b) Device common name

×

c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion

×

Comments? Pages 5 to 10, Page 17

3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also [21 CFR 801.109](#)).

×

×

Comments? Page 14

4) Submission contains 510(k) Summary or 510(k) Statement

×

×

a) Summary contains all elements per [21 CFR 807.92](#) (See also [510\(k\) Summary Checklist](#))

×

b) Statement contains all elements per [21 CFR 807.93](#)

×

Comments? Pages 17 to 18

5) Submission contains Truthful and Accuracy Statement per [21 CFR 807.87\(k\)](#) See recommended [format](#)

×

×

Comments? Page 19

6) Submission contains Class III Summary and Certification. See recommended [content](#).

×

×

Comments? Page 21

7) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s ([Form 3654](#)) or includes detailed information about how and the extent to which the standard has been followed.

×

×

Comments? Page 72

8) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.

×

×

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

	Yes	No	N/A	Comment
--	-----	----	-----	---------

a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance " Medical Devices: The Pre-Submission Program and Meetings with FDA Staff. " Once finalized, this guidance will represent the Agency's current thinking on this topic.			×	
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Comments? Page 22

B. Device Description

9)

a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			×	
--	--	--	---	--

b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			×	
--	--	--	---	--

10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				×
--	--	--	--	---

a) A description of the principle of operation and mechanism of action for achieving the intended effect.	×			
---	---	--	--	--

b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	×			
---	---	--	--	--

c) A list and description of each device for which clearance is requested.	×			
--	---	--	--	--

Comments? Pages 22 to 30

11) A description of all device modification(s) including rationale for each modification.	×			×
--	---	--	--	---

Comments? Pages 22 to 23, Pages 26 to 30

12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	×			×
---	---	--	--	---

Comments? Page 24

13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system			×	
--	--	--	---	--

C. Substantial Equivalence Discussion

14) Submitter has identified a predicate device.	×			×
--	---	--	--	---

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
---	-----	----	-----	---------

a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is available online.</i>	×			
--	---	--	--	--

b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.				
---	--	--	--	--

Comments? Page 22

15) Submission includes a comparison of the following for the predicate(s) and subject device				×
---	--	--	--	---

a) Indications for Use	×			
------------------------	---	--	--	--

b) Technology, including features, materials, and principles of operation	×			
---	---	--	--	--

Comments? Pages 26 to 30

16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	×			×
--	---	--	--	---

Comments? Page 27

D. Design Control Activities

17) Design Control Activities Summary includes all of the following:				×
--	--	--	--	---

a) Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components AND the results of the analysis.	×			
---	---	--	--	--

b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.	×			
--	---	--	--	--

c) Declaration of conformity with design controls, including: <i>All 3 must be present to answer "Yes."</i> i. Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met. ii. Statement that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 . iii. Statement is signed by the individual responsible for these activities.	×			
--	---	--	--	--

Comments? Page 33, Pages 67 to 68

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision.
 - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.

Yes

No

N/A

Comment

E. Proposed Labeling (see also 21 CFR part 801)

18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	×			×
a) All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.	×			
Comments? Pages 37 to 55				
19) Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).	×			×
Comments? Page 22				

Decision: Accept Refuse to Accept
Records processed under FOIA Request # 2015-6305; Released by CDRH on 12-03-2015

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off

Branch Chief Sign-Off
(digital signature
optional)*

Division Sign-Off
(digital signature
optional)*

* Branch and Division review of checklist and concurrence with with decision required.
Branch and Division digital signature optional.

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

The Medical Device User Fee Cover Sheet (b)(4) for this device is provided on the following page.

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. 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/cover sheet.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 Kweku Biney 2.1 E-MAIL ADDRESS kbiney@its.jnj.com 2.2 TELEPHONE NUMBER (include Area code) 513-337-3135 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm <u>Select an application type:</u> <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"/> 30-Day Notice		
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		
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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 the address below. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		
		20-Apr-2015

Form FDA 3601 (05/13)

"Close Window" [Print Cover sheet](#)

Section 2: CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)

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

FOOD AND DRUG ADMINISTRATION

OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on page 5.

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 05/15/2015	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)
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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 type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Request for Feedback <input type="checkbox"/> Pre-Submission <input type="checkbox"/> Informational Meeting <input type="checkbox"/> Submission Issue Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Study Risk Determination <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)(6)			
Contact Title Senior Director, Quality Operations		Contact E-mail Address (b)(4)	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name Ethicon Endo-Surgery, Inc.			
Division Name (if applicable) N/A		Phone Number (including area code) (513) 337-7623	
Street Address 4545 Creek Road		FAX Number (including area code) (513) 337-2623	
City Cincinnati	State / Province OH	ZIP Code 45242	Country USA
Contact Name Brian Godwin			
Contact Title Senior Regulatory Affairs Associate		Contact E-mail Address bgodwin@its.jnj.com	

SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR NDE

<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

Other Reason (*specify*):

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		

Other Reason (*specify*):

SECTION D3

REASON FOR SUBMISSION - 510(k)

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
--	---	---

Other Reason (*specify*):

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 <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	LFL	2		3		4		
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	K133314	HARMONIC® Focus Shears + Adaptive Tissue Technology	Ethicon Endo-Surgery, LLC
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name
Classification Name: Instrument, Ultrasonic Surgical

	Trade or Proprietary or Model Name for This Device	Model Number
1	HARMONIC® Focus Long Shears + Adaptive Tissue Technology	1 HAR17F
2		2
3		3
4		4
5		5

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

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code LFL	C.F.R. Section (if applicable) Unassigned	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General and Plastic Surgery		

Indications (from labeling)
The HARMONIC FOCUS® Long Shears + Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, otorhinolaryngologic (ENT), plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open procedures.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FD-305, and Number (if known)

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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 3005075853	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Ethicon Endo-Surgery, LLC		Establishment Registration Number 300507853		
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 Code 00969	Country USA
Contact Name (b)(6)		Contact Title Senior Quality Operations Director		Contact E-mail Address (b)(4)

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number (b)(4)	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input checked="" type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
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(b)(4), (b)(6)

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number (b)(4)	<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
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(b)(4), (b)(6)

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	60601-1	IEC	IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	2005	12/1/2005
2	60601-1-2	IEC	IEC 60601-1-2:2007, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility	2007	3/1/2007
3	10993-7	AAMI ANSI ISO	ISO 10993-7:2008, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals	2008	12/10/2008
4	EN ISO 11135-1:2014	AAMI ANSI ISO	11135:2014, Medical Devices - Validation & Routine Control of Ethylene Oxide Sterilization	2014	7/15/2014
5	10993-1	AAMI ANSI ISO	ISO 10993:2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2009	10/15/2009
6					
7					

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
 Food and Drug Administration
 Office of Chief Information Officer
 Paperwork Reduction Act (PRA) Staff
 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.



15 May 2015

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: **Special 510(k) Premarket Notification:**
Ethicon HARMONIC® Focus Long Shears + Adaptive Tissue Technology

Dear Sir or Madam:

Pursuant to 21 CFR 807.90, Ethicon Endo-Surgery is submitting two copies of this Special 510(k) premarket notification for the Ethicon HARMONIC Focus Long Shears + Adaptive Tissue Technology. The design of the new device is based upon the predicate device HARMONIC Focus Shears + Adaptive Tissue Technology device, cleared under K133314 on 03 December 2013.

This subject device has never been submitted to the FDA before. There are no prior 510k submissions for the subject device. This is a new 510(k) submission. The subject device is not an *in vitro* diagnostic device.

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

Submission Type: Special 510(k)
Device Common Name: Instrument, Ultrasonic Surgical
Classification Name: Instrument, Ultrasonic Surgical
510(k) Submitter: Ethicon Endo-Surgery, LLC

Contact Person: Brian Godwin, RAC
Senior Regulatory Affairs Associate
Phone: (513) 337-3623
Fax: (513) 337-4366
Email: bgodwin@its.jnj.com

Confidentiality Preference: Please keep this submission confidential per 21 CFR 807.95
Classification Regulations: Unassigned
Device Class: Class II
Panel: General & Plastic Surgery
Classification Codes: LFL
Related FDA Document Numbers K133314

Payment of the user fee has been made. A unique payment identification number (PIN) has been assigned to this submission, it is (b)(4) [REDACTED]. A copy of the Medical Device User Fee Cover Sheet has been included in Section I for reference.

Per the instructions contained in the guidance *Electronic Copies for Pre-Market Submissions*, an electronic copy is being provided with this submission that is an exact duplicate of the paper copy.

If there are any questions concerning this notification, please contact me at (513) 337-3623 or by email at bgodwin@its.jnj.com. If I am not available, the alternate contact person for this submission is Hortense Allison, Director, Regulatory Affairs, at (513) 337-3592.

Sincerely,



Brian Godwin, RAC
Senior Regulatory Affairs Associate

Enclosure

Section 4: Indications for Use Statement (FDA Form 3881)

The Indications for Use Statement for the proposed device is provided on the following page.

Indications for Use

510(k) Number (if known)

Device Name

HARMONIC FOCUS® Long Shears + Adaptive Tissue Technology

Indications for Use (Describe)

The HARMONIC FOCUS® Long Shears + Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, otorhinolaryngologic (ENT), plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open procedures.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 number."

Section 5: 510(k) Summary or 510(k) Statement

The 510(k) Summary of Safety and Effectiveness Information for the proposed device is on the following pages.

510(k) Summary

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

Contact Brian Godwin, RAC
Senior Regulatory Affairs Associate
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, OH 45242
Telephone: (513) 337-3623
Fax: (513) 337-4366
Email: bgodwin@its.jnj.com

Date Prepared 15 May 2015

Device Name

Trade Name: HARMONIC FOCUS[®] Long Shears + Adaptive Tissue Technology
Common Name: Instrument, Ultrasonic Surgical
Model Number: HAR17F

Classification Name

Instrument, Ultrasonic Surgical (Unassigned, Product Code LFL)

Predicate Device

HARMONIC FOCUS[®] Shears + Adaptive Tissue Technology, cleared under K133314 on 03 December 2013

Device Description

The HARMONIC FOCUS+ Long Shears is a sterile, single patient use instrument consisting of a soft grip scissor handle housing assembly with two hand controls (MIN for minimum power level and MAX for maximum power level). The instrument has a curved blade and clamp arm with teflon pad. Measured from the blade tip to the MAX hand control power button, the instrument is 17 cm in length with a 16 mm active blade length. The HARMONIC FOCUS+ Long Shears instrument allows for the cutting and coagulation of vessels up to and including 5 mm in diameter.

Indications for Use

The HARMONIC FOCUS Long Shears + Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, otorhinolaryngologic (ENT), plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open procedures.

Technological Characteristics

The subject and predicate devices use the same ultrasonic technology to perform their intended use. Both devices use the HPBLUE handpiece to convert electrical energy into ultrasonic vibration.

The ergonomic differences between the subject and predicate devices are attributable to the respective design of each. Additionally, the subtle difference in the blade frequency upper bound is due to the increased blade length and has no clinical relevance with regards to tissue effect. These differences were found to not affect safety or effectiveness via design verification activities.

Performance Data

Ex-vivo tests were performed to ensure that the subject device performs as intended and meet design specifications. Device performance was assessed against the design requirements, and included process verification, design verification, and design validation.

Clinical Studies

This premarket notification does not rely on human clinical trial data to demonstrate substantial equivalence.

Conclusion

This modification of the predicate device revealed no new issues of safety or efficacy as demonstrated through design validation and verification studies. The HARMONIC Focus Long Shears + Adaptive Tissue Technology are as safe and effective and perform as well as the identified legally marketed predicate devices for cutting and coagulating soft tissue and sealing vessels up to 5 mm in diameter, as measured *in situ*.

Section 6: Truthful and Accuracy Statement

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

Ethicon Endo-Surgery, LLC
510(k) Premarket Notification (Special)

HARMONIC FOCUS® Long Shears + Adaptive Tissue Technology

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 Senior Regulatory Affairs Associate for Ethicon, 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 has been omitted.



Brian Godwin, RAC
Senior Regulatory Affairs Associate
Ethicon, Inc.

15 MAY 15
Date

510(k) Number

Section 7: Class III Summary and Certification

This section does not apply; the Ethicon HARMONIC[®] Focus Long Shears + Adaptive Tissue Technology is a Class II device.

Section 8: Device Information and Description of Modification

This Special 510(k) is for minor design modifications to the identified predicate device, HARMONIC Focus Shears + Adaptive Tissue Technology (HAR9F), cleared under K133314 on 03 December 2013. The name of the subject device is HARMONIC Focus Long Shears + Adaptive Tissue Technology (HAR17F).

This subject device has never been submitted to the FDA before. There are no prior 510(k) submissions for the subject device; this is a new 510(k) submission. The subject device is not an *in vitro* diagnostic device.

The intended use of the modified device has not changed from the legally marketed predicate device, nor has the device fundamental scientific technology changed. The predicate is available in a 9 cm working length. The working length of the modified device is being increased to 17 cm. The modified device was tested in accordance with design controls and found to perform equivalently to the identified predicate device.

Device Trade Name HARMONIC FOCUS® Long Shears + Adaptive Tissue Technology

Model Number HAR17F

Device Class Class II

Panel General and Plastic Surgery

Product Code LFL

Classification Name Instrument, Ultrasonic Surgical (Unclassified)

Address and Registration

Legal Manufacturer	Sterilization Site
Ethicon Endo-Surgery, LLC 475 Calle C Guaynabo, Puerto Rico 00969 USA	(b)(4)

Predicate Device Information HARMONIC Focus Shears + Adaptive Tissue Technology (HAR9F), cleared under K133314 on 03 December 2013.

Sterilization Sterilized via (b)(4)

Shelf Life 5 years

Device Modifications

This Special 510(k) is for minor design modifications to the identified predicate device to increase the working length of the device. The working length of the predicate device is 9 cm; the working length of the subject device has been increased to 17 cm. This modification of lengthening the device via design verification revealed no new issues of safety or efficacy.

(b)(4)

Figures 8-1 and 8-2 show the subject and predicate devices, respectively. The following pages are dimensional engineering drawings of the subject and predicate device, respectively.

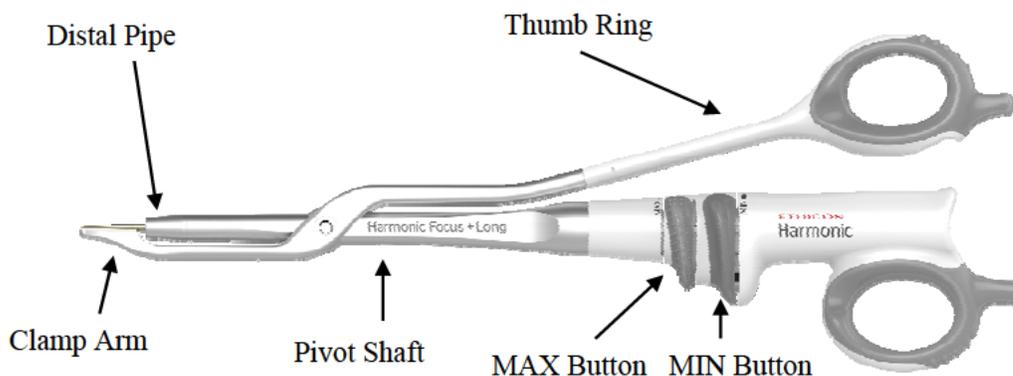


Figure 8-1: HARMONIC Focus Long Shears + Adaptive Tissue Technology

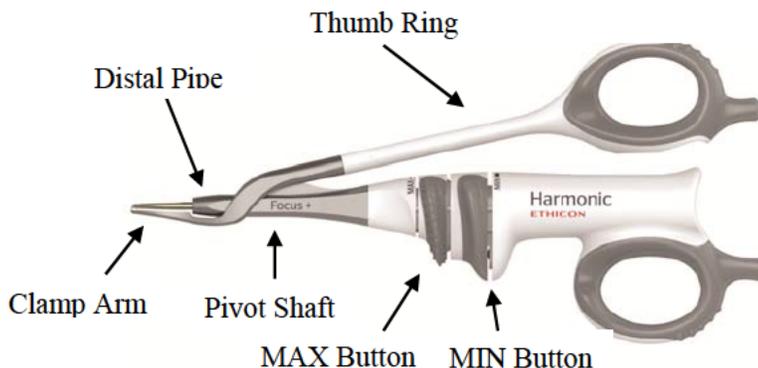


Figure 8-2: HARMONIC Focus Shears + Adaptive Tissue Technology

Table 8-1 presents a description of the proposed design modifications, Table 8-2 presents a comparison of the indications and contraindications for the subject and predicate device, and Table 8-3 presents a comparison table of the technology and performance specifications for the subject and predicate devices.

Table 8-1: Proposed Design Modifications

Change	Component	Description
Dimensional Changes	Clamp Arm Assembly	Increased working length from 9 cm to 17 cm, through individual component changes below.
	Clamp Arm	Increased length from 6.4 cm to 14.8 cm
	Pivot Shaft	Increased length from 4.1 cm to 11.8 cm
	Distal Pipe	Slimmer cosmetic profile at the distal portion for added surgeon visibility.

(b)(4)

Table 8-2: Device Comparison Table – Indications for Use and Contraindications

<i>Indications for Use</i>	
HARMONIC FOCUS Long Shears + Adaptive Tissue Technology <i>(subject device)</i>	HARMONIC FOCUS Shears + Adaptive Tissue Technology <i>(predicate device)</i>
The HARMONIC FOCUS Long Shears + Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, otorhinolaryngologic (ENT)*, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open procedures.	Same

<i>Contraindications</i>	
HARMONIC FOCUS Long Shears + Adaptive Tissue Technology <i>(subject device)</i>	HARMONIC FOCUS Shears + Adaptive Tissue Technology <i>(predicate device)</i>
<ul style="list-style-type: none"> • The instruments are not indicated for incising bone. • The instruments are not intended for contraceptive tubal occlusion. 	Same

(b)(4)

Technology and Performance

The HARMONIC Focus Long Shears + Adaptive Tissue Technology device works with the Generator G11 as part of a system. The device system has three essential parts: the Generator G11 (GEN11), the handpiece (HPBLUE), and the single-use subject device (HAR17F). The subject device uses an external torque wrench for assembly to the HPBLUE handpiece.

The HPBLUE handpiece (used by both the subject [HAR17F] and predicate [HAR9F] device) connects the devices to the Generator G11, and converts electronic energy into ultrasonic vibration. The high-frequency mechanical vibration at (b)(4) in the HARMONIC Focus+ Long device blade cuts and coagulates tissue, and seals vessels up to 5 mm. This ultrasonic vibration is a form of mechanical energy, and no electricity passes to or through the patient. There have been no changes to the operating principles and fundamental scientific technology of the predicate and the subject device; they are the same.

(b)(4)

Table 8-3: Device Comparison Table – Technology and Performance Specifications

Device Characteristic	HARMONIC Focus Long Shears + Adaptive Tissue Technology <i>(subject device)</i>	HARMONIC Focus Shears + Adaptive Tissue Technology <i>(predicate device)</i>
Product Code	HAR17F	HAR9F
Sterility Method (Device & Torque Wrench)	(b)(4)	
Sterility Assurance Level (SAL)	(b)(4)	

Device Characteristic	HARMONIC Focus Long Shears + Adaptive Tissue Technology (subject device)	HARMONIC Focus Shears + Adaptive Tissue Technology (predicate device)
Patient Use	Single Use	Same
Max Power	(b)(4)	Same
Max Voltage	(b)(4)	Same
Max Current	(b)(4)	Same
Blade Frequency	(b)(4)	55,500±500 Hz
Maximum Blade Amplitude (MAX Power Level)	(b)(4)	Same
Instrument Working Length	17 cm	9 cm
Active Blade Length	(b)(4)	Same
Jaw Aperture	(b)(4)	(b)(4)
Thumb Ring Clamp Force	(b)(4)	(b)(4)
Grasping Force	(b)(4)	(b)(4)
Packaging	Flexible form filled seal blister	Same
Energy Activation Method	Foot or Hand Switch	Same
Maximum Indicated Vessel Size	5 mm	Same
Handle Type	Hemostat-like	Same
Identification	(b)(4)	Same
Available Generator Tones	(b)(4)	Same
Torque Wrench	Disposable, included	Same

(b)(4) Manufacturing Information



Device Description

The HARMONIC FOCUS+ Long Shears is a sterile, single patient use instrument consisting of a soft grip scissor handle housing assembly with two hand controls (MIN for minimum power level and MAX for maximum power level). The instrument has a curved blade and clamp arm with teflon pad. Measured from the blade tip to the MAX hand control power button, the instrument is 17 cm in length with a 16 mm active blade length. The HARMONIC FOCUS+ Long Shears instrument allows for the cutting and coagulation of vessels up to and including 5 mm in diameter.

Table 8-4 presents a summary of the patient contacting materials in the subject device and predicate device.

Table 8-4: Device Comparison Table – Patient Contact Materials

Component	HARMONIC Focus Long Shears + Adaptive Tissue Technology <i>(subject device)</i>	HARMONIC Focus Shears + Adaptive Tissue Technology <i>(predicate device)</i>
Blade	(b)(4)	
Clamp Arm		
Clamp Arm Anodization		
Clamp Pad		
Pivot Shaft		
Pivot Shaft Anodization		
Pad Print		
Shroud		
Pivot Shaft		
Bearing Retainer		
Bearing Retainer Anodization		
Thumb Ring		
Thumb Ring Overmold		
Thumb Ring Pin		
Distal Pipe		
Distal Pipe Anodization		
Handle Shroud		
Handle Shroud Overmold		
Distal Trigger Shroud		
Distal Trigger Shroud Overmold		
Distal Trigger Cap		
Distal Trigger Cap Overmold		
Proximal Trigger Shroud		

Component	HARMONIC Focus Long Shears + Adaptive Tissue Technology (subject device)	HARMONIC Focus Shears + Adaptive Tissue Technology (predicate device)
	(b)(4)	
Proximal Trigger Shroud Overmold		
Proximal Trigger Cap		
Proximal Trigger Cap Overmold		
Shroud Cap		
Proximal and Distal Trigger Lubricant		

Labeling

Minor labeling modifications are being proposed for the subject device based on the design modification. Table 8-5 presents a summary of the differences between the subject and predicate IFUs by section.

The differences between the subject and predicate IFUs are presented here in **bold**. Indications for use and intended use are unchanged from the predicate device.

Labeling and Instructions for Use (IFU) can be found in Section 10. These areas have been highlighted in yellow in the subject device IFU and a copy of the subject device IFU has been provided, both for reviewer convenience.

Table 8-5: Summary of Instructions for Use Differences – Subject (HAR17F) and Predicate (HAR9F) Device

HARMONIC Focus Long Shears + Adaptive Tissue Technology (HAR17F) (subject device)	HARMONIC Focus Shears + Adaptive Tissue Technology (HAR9F) (predicate device)
<i>Throughout</i>	
<p>Purple torque wrench</p> <p>Note: Due to the increased length of the subject device, a different torque wrench is required to sufficiently torque the device onto the handpiece during assembly and off of during disassembly. As a result, the subject device IFU makes reference to a purple torque wrench, not a gray torque wrench, where appropriate.</p>	<p>Gray torque wrench</p>

HARMONIC Focus Long Shears + Adaptive Tissue Technology (HAR17F) <i>(subject device)</i>	HARMONIC Focus Shears + Adaptive Tissue Technology (HAR9F) <i>(predicate device)</i>
<i>Device Description</i>	
The HARMONIC FOCUS+ Long Shears is a sterile, single patient use instrument consisting of a soft grip scissor handle housing assembly with two hand controls (MIN for minimum power level and MAX for maximum power level). The instrument has a curved blade and clamp arm with teflon pad. Measured from the blade tip to the MAX hand control power button, the instrument is 17 cm in length with a 16 mm active blade length. The HARMONIC FOCUS+ Long Shears instrument allows for the cutting and coagulation of vessels up to and including 5 mm in diameter.	The HARMONIC FOCUS+ Shears is a sterile, single patient use instrument consisting of a soft grip scissor handle housing assembly with two hand controls (MIN for minimum power level and MAX for maximum power level). The instrument has a curved blade and clamp arm with teflon pad. Measured from the blade tip to the MAX hand control power button, the instrument is 9 cm in length with a 16 mm active blade length. The HARMONIC FOCUS+ Shears instrument allows for the cutting and coagulation of vessels up to and including 5 mm in diameter.
<i>Warnings and Precautions</i>	
Federal (USA) law restricts this device to sale by or on the order of a physician.	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
Avoid accidental contact with other instruments during use. Scratches on the blade may lead to premature blade failure.	Scratches on the blade may lead to premature blade failure.
<i>Illustrations and Nomenclature</i>	
6. Finger Ring Rests	N/A
<i>Assembly, Step 3</i>	
Use the purple torque wrench to tighten the instrument onto the hand piece. Turn the wrench clockwise while holding the Hand Piece until it clicks twice, indicating that sufficient torque has been applied to secure the instrument (Illustration 3). In the event that the torque wrench must be re-positioned on the instrument, ensure that the torque wrench is re-positioned correctly, as shown in Illustration 3. When properly aligned, the short side of the torque wrench should be aligned with the instrument hand controls, handle housing, and the Hand Piece, and the	Use the Gray Torque Wrench to tighten the instrument onto the Hand Piece. Turn the wrench clockwise while holding the Hand Piece until it clicks twice, indicating that sufficient torque has been applied to secure the instrument (Illustration 3). To ensure properly assembly, do not grip the instrument handle while applying torque with the Torque Wrench. Caution: Do not torque the instrument by hand or damage may occur to the Hand Piece. Do not use any means other than the Torque Wrench to attach or detach the instrument from the Hand Piece.

HARMONIC Focus Long Shears + Adaptive Tissue Technology (HAR17F) <i>(subject device)</i>	HARMONIC Focus Shears + Adaptive Tissue Technology (HAR9F) <i>(predicate device)</i>
<p>“Dispose of Properly” icon on the torque wrench should be on top. To ensure properly assembly, do not grip the instrument handle while applying torque with the Torque Wrench.</p> <p>Caution: Do not torque the instrument by hand or damage may occur to the Hand Piece. Do not use any means other than the Torque Wrench to attach or detach the instrument from the Hand Piece.</p>	
<p><i>Operation, Step 7</i></p>	
<p>Close the clamp arm and insert the instrument through the incision. Use the HARMONIC FOCUS+ Long Shears for dissection, grasping, coagulation, and cutting between the blade and clamp arm. Use the top of the blade with the jaws open if using for backcutting. Caution: Do not use finger ring rests to extend reach during procedure, as this could result in poor vessel sealing and unstable positioning of the instrument (Illustration 9).</p> <p>WARNING: Keep the jaws of the device open when backcutting or while the blade is active without tissue between the blade and tissue pad, to avoid damage to the tissue pad, and increased blade, clamp arm, and distal shaft temperatures.*</p>	<p>Close the clamp arm and insert the instrument through the incision. Use the Harmonic Focus®+ Shears for dissection, grasping, coagulation, and cutting between the blade and clamp arm. Use the top of the blade with the clamp arm open if using for backcutting.</p> <p>WARNING: Keep the clamp arm open when backcutting or while the blade is active, without tissue between the blade and tissue pad, to avoid damage to the tissue pad.*</p>

*These “WARNING” statements are bold in their respective IFUs. The difference here has been *italicized* for reviewer convenience.

Section 9: Summary of Design Control Activities

Table 9-1 presents a summary of design verification and validation testing. The same parameters were evaluated for HAR9F and included in K133314, cleared on 03 December 2013.

Performance Test	Acceptance Criteria	Result
(b)(4)		

Risk Analysis Methodology

(b)(4)

Section 10: Labeling

This section contains the draft device labels and Instructions for Use (IFU) for the Ethicon Endo-Surgery HARMONIC FOCUS Long Shears + Adaptive Tissue Technology.

The labeling contained in this section includes:

- Subject Device (HAR17F)
 - Figure 10-1 Draft Tyvek Label
 - Figure 10-2 Draft Carton Label
 - Draft Instructions for Use
- Predicate Device (HAR9F) Instructions for Use (for reviewer convenience)

ETHICON Harmonic	HARMONIC FOCUS®	+ Adaptive Tissue Technology	17 cm Length	REF QTY 1
	Long Shears			HAR17F Catalogue Number

A000115P00

HARMONIC FOCUS® Long Shears, +Adaptive Tissue Technology, 17cm Length
 Ciseaux longs HARMONIC FOCUS®, + technologie tissulaire adaptative, 17 cm de long
 HARMONIC FOCUS® Lange Koagulationsschere, +Adaptive Gewebetechologie, 17 cm lang
 Forbici lunghe HARMONIC FOCUS®, +tecnologia adattativa al tessuto, lunghezza 17 cm
 Tesoura Comprida + Tecnologia Adaptativa aos Tecidos HARMONIC FOCUS®, 17 cm de comprimento
 Tijeras largas HARMONIC FOCUS®, +Tecnología de adaptación tisular, Longitud 17 cm
 HARMONIC FOCUS® lange schaar, +adaptieve weefseltechnologie, lengte 17 cm
 HARMONIC FOCUS® Uzun Makas, +Adaptif Doku Teknolojisi, 17 cm Uzunluk
 HARMONIC FOCUS® ロングシアーズ、+アダプティブ ティッシュ テクノロジー、17cm 長




STERILIZED BY ETHYLENE OXIDE

- Single Patient Use
- Do Not Re-sterilize
- Do Not Use if Sterile Package is Damaged
- See Instructions for Use

CE 0128

Blue Only For Use with BLUE Hand Piece ONLY

Ethicon Endo-Surgery, LLC
475 Cole C
Cincinnati, OH 45209 USA
©Ethicon Endo-Surgery, Inc. 2014
Assembled in Mexico

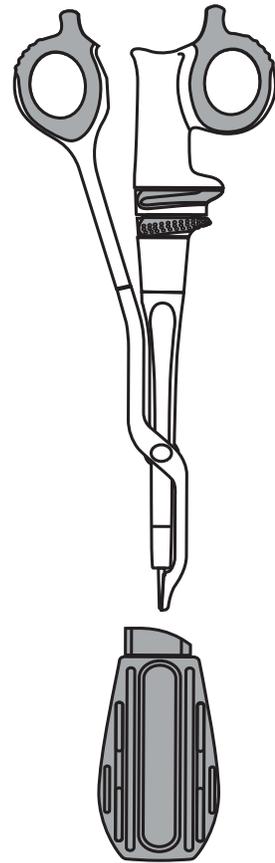
Figure 10-1: Draft Tyvek Label – HAR17F



Figure 10-2: Draft Carton – HAR17F

Instructions for Use – HAR17F

HARMONIC FOCUS® Long Shears + Adaptive Tissue Technology
Ciseaux HARMONIC FOCUS® + Technologie Tissulaire Adaptive
HARMONIC FOCUS® Koagulationsschere + Adaptive Tissue Technology
Forbici HARMONIC FOCUS® + tecnologia adattativa al tessuto
Tesoura HARMONIC FOCUS® + Tecnologia Tecidual Adaptável
Cizallas HARMONIC FOCUS® + Tecnología adaptativa tisular
HARMONIC FOCUS®-schaar + adaptieve weefseltechnologie
HARMONIC FOCUS® saks + adaptiv vævsteknologi
HARMONIC FOCUS® -sakset + mukautuva kudostekniikka
Ψαλίδι HARMONIC FOCUS® + Προσαρμοζόμενη τεχνολογία ιστού
HARMONIC FOCUS® sax + adaptiv vävnadsteknologi
Nożyce HARMONIC FOCUS® + adaptacyjna technologia tkankowa
HARMONIC FOCUS® metsző + adaptív szövettechnológia
Nůžky HARMONIC FOCUS® + s adaptivní tkáňovou technologií
Nožnice HARMONIC FOCUS® + s adaptívnou tkanivovou technológiou
HARMONIC FOCUS® 多用剪 + 自适应组织技术



Please read all information carefully.

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

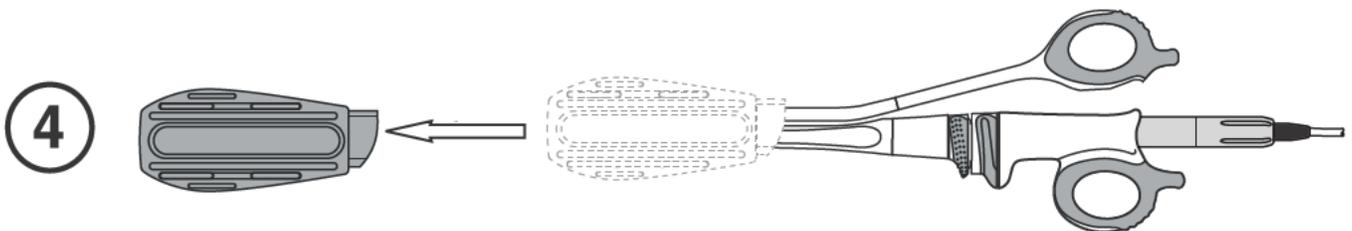
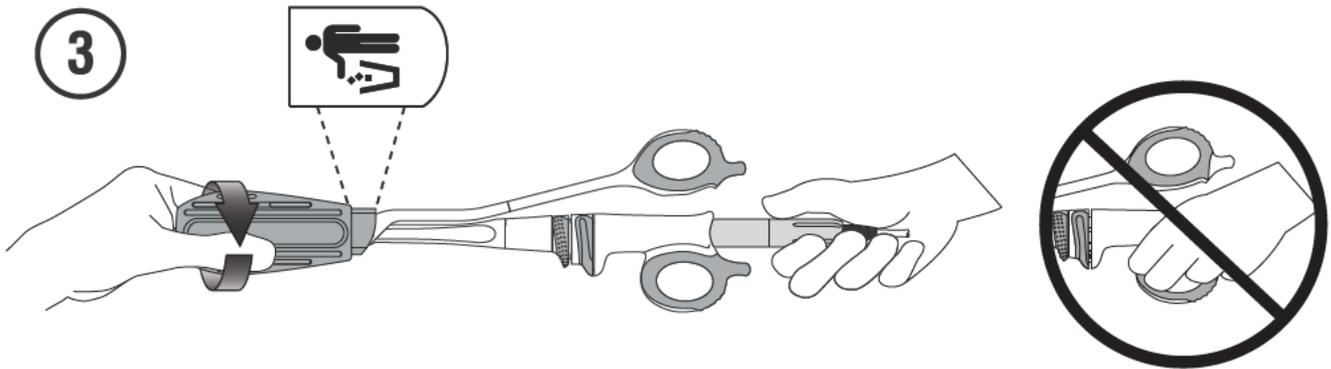
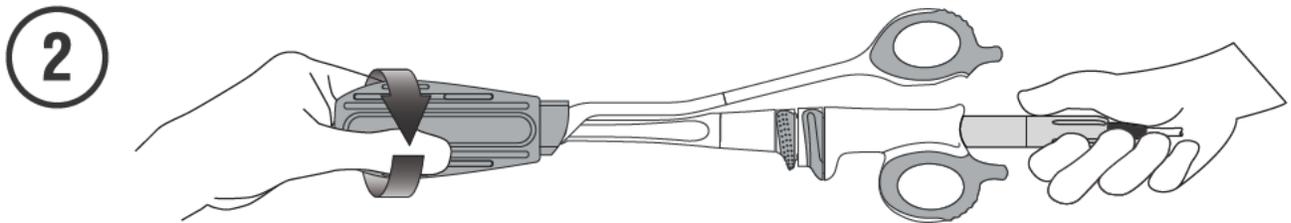
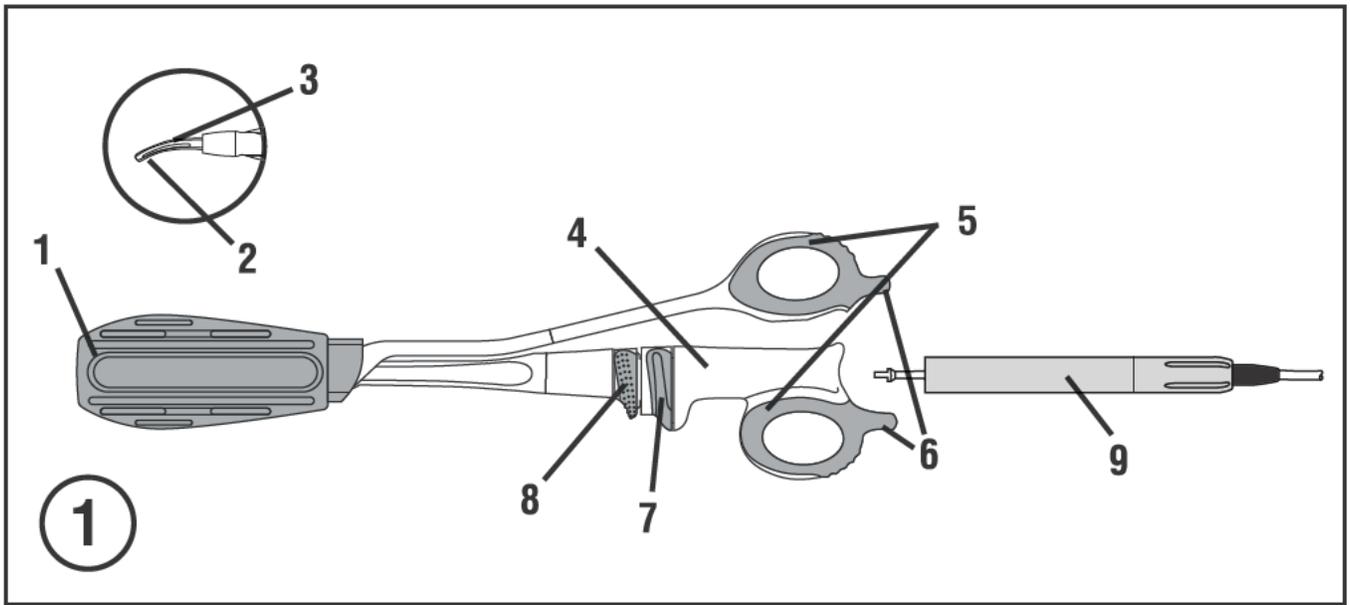
Important: This package insert is designed to provide instructions for use of the HARMONIC FOCUS® Long Shears + Adaptive Tissue Technology. It is not a reference to ligation techniques.

HARMONIC, HARMONIC FOCUS and ULTRACISION are trademarks of Ethicon Endo-Surgery.

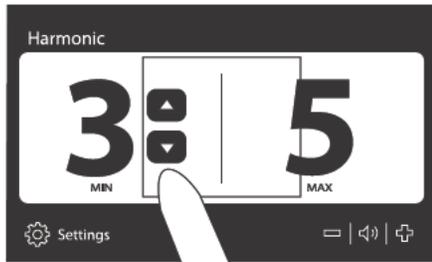
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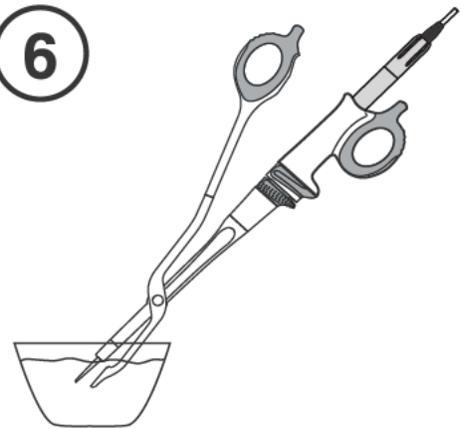
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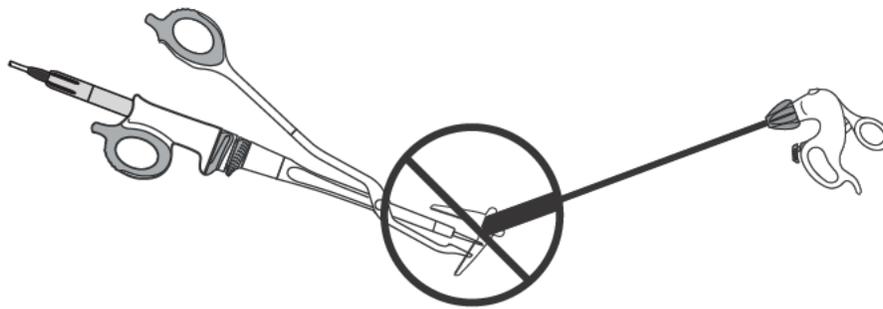
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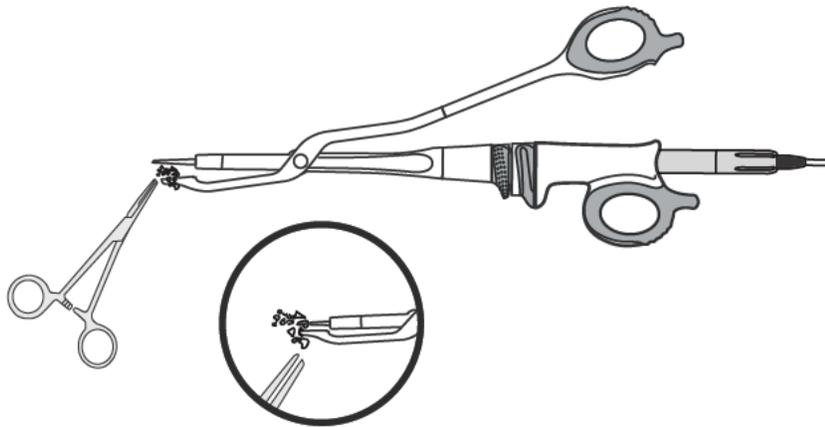
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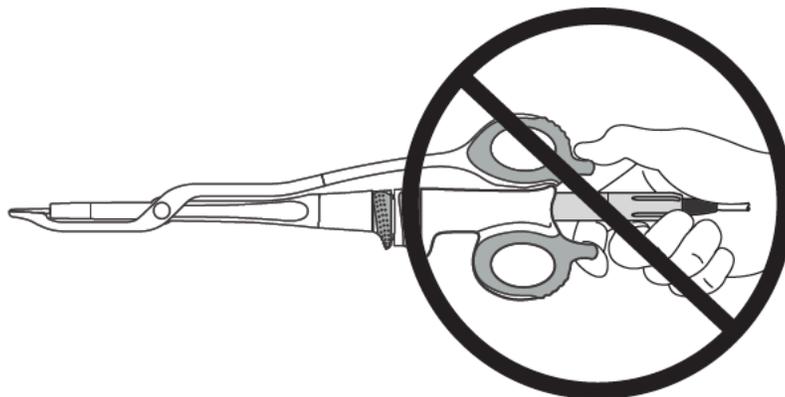
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Indications

The HARMONIC FOCUS® Long Shears + Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, otorhinolaryngologic (ENT), plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open procedures.

Contraindications

- The instrument is not indicated for incising bone.
- The instrument is not intended for contraceptive tubal occlusion.

Warnings and Precautions

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- 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 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 instruments in liquid unless the instruments are designed and labeled to be immersed.
- Verify compatibility with generators. HARMONIC FOCUS+ Long Shears are compatible only with Ethicon Endo-Surgery Generator G11 (GEN11) software version 2013_1 or later. Software revision can be found under “System Information” in the Generator G11 (GEN11) “Settings” Menu. Refer to the Generator G11 (GEN11) Operator’s Manual for more information.
- Audible high-pitched ringing, resonating from the blade or Hand Piece, are an abnormal condition and an indicator that the blade or hand piece is not operating properly. The ringing may be an indicator that the hand piece is beyond its useful life or that the blade has not been attached properly, which may result in abnormally high shaft temperatures and user or patient injury.
- In case of system failure, ensure the availability of the appropriate back-up equipment relevant to the specific procedure.
- Blood and tissue buildup between the blade and shaft may result in abnormally high temperatures at the distal end of the shaft. To prevent burn injury, remove any visible tissue buildup at the distal end of the shaft.
- As with all energy sources (Electrosurgery, Laser, or Ultrasound), there are concerns about the carcinogenic and infectious potential of the by-products, such as tissue smoke plume and aerosols. Appropriate measures such as protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
- Do not attempt to bend, sharpen, or otherwise alter the shape of the blade. Doing so may cause blade failure and user or patient injury.
- To avoid user or patient injury in the event that accidental activation occurs, the instrument blade, clamp arm, and distal end of the shaft should not be in contact with the patient, drapes, or flammable materials while not in use.
- During and following activation in tissue, the instrument blade, clamp arm, and distal portion of the shaft may become hot. Avoid unintended contact with tissue, drapes, surgical gowns, or other unintended sites at all times.
- Incidental and prolonged activation against solid surfaces, such as bone, may result in blade heating and subsequent blade failure, and should be avoided.

- Avoid contact with any and all metal or plastic instruments or objects when the instrument is activated. Contact with staples, clips, or other instruments while the instrument is activated may result in cracked or broken blades, which may be identified by generator solid tone or instrument error.
- Avoid accidental contact with other instruments during use. Scratches on the blade may lead to premature blade failure.
- Care should be taken not to apply pressure between the instrument blade and tissue pad without having tissue between them. Clamping the tissue pad against the active blade without tissue on the full length of the blade will result in higher blade, clamp arm and distal shaft temperatures and can result in possible damage to the instrument. If this happens, there may be a system failure signaled by a continuous tone or alert screen when either of the foot pedals or hand control buttons is depressed.
- Keep the jaws of the device open when backcutting or while the blade is active without tissue between the blade and tissue pad, to avoid damage to the tissue pad and increased blade, clamp arm, and distal shaft temperatures.
- To avoid user or patient injury, do not activate an electrosurgical device in close proximity to the HARMONIC® instruments. The aerosols created by the activation of the HARMONIC instruments in fatty tissue are potentially flammable.
- The entire exposed blade tip and any exposed blade shaft is active and will cut/coagulate tissue when the HARMONIC FOCUS+ Long Shears blade is activated. Be careful to avoid inadvertent contact between all exposed blade surfaces and surrounding tissue when using the HARMONIC FOCUS+ Long instrument.
- Use only the HARMONIC® Foot Switch, and the Blue Hand Piece, with the HARMONIC FOCUS+ Long Shears instrument to ensure compatibility with the Generator.
- After removing the instrument, examine the tissue for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- The sealing performance of this instrument has not been assessed on arteriosclerotic vessels. Exercise caution when transecting these vessels as they may not seal properly.
- Minimum starting power level defaults to power level 3.
- Successful hemostasis may require adjunct measures when HARMONIC FOCUS+ Long Shears instruments are used on solid organs. Due to the difficulty of visualizing internal structures, proceed slowly and do not attempt to transect large masses of tissue in one activation. Avoid the division of large vascular/biliary bundles when using the HARMONIC FOCUS+ Long Shears instrument under these conditions.
- Products manufactured or distributed by companies not authorized by Ethicon Endo-Surgery may not be compatible with the HARMONIC FOCUS+ Long Shears instrument. Use of such products may lead to unanticipated results and possible injury to the user or patient.
- Do not torque the instrument by hand or damage may occur to the hand piece. Do not use any means other than the torque wrench to attach or detach the instrument from the hand piece.
- Take care to avoid damage to the shears when removing the torque wrench from the instrument.
- Take care to avoid injury from the blade tip while removing the torque wrench from the instrument
- Do not clean the instrument with abrasives.
- 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. Multiple patient use may compromise the device integrity or create a risk of contamination that, in turn, may result in patient injury or illness.

Device Description

The HARMONIC FOCUS+ Long Shears is a sterile, single patient use instrument consisting of a soft grip scissor handle housing assembly with two hand controls (MIN for minimum power level and MAX for maximum power level). The instrument has a curved blade and clamp arm with teflon pad. Measured from the blade tip to the MAX hand control power button, the instrument is 17 cm in length with a 16 mm active

blade length. The HARMONIC FOCUS®+ Long Shears instrument allows for the cutting and coagulation of vessels up to and including 5 mm in diameter.

Each HARMONIC FOCUS+ Long Shears instrument is packaged with one sterile, single patient use, disposable purple torque wrench. Use only the purple torque wrench with the HARMONIC FOCUS+ Long Shears instrument. The torque wrench should not be discarded until the completion of the surgical case. Do not attempt to sterilize the disposable torque wrench.

The two dashes on the instrument are intended to represent relative vessel size. The MAX  button is typically used for smaller vessels where cutting speed is fastest. The MIN  button is typically used in slightly larger vessels and has reduced cutting speed. It is indicated for vessels up to 5 mm in size. Adaptive Tissue Technology provides the generator with the ability to identify and monitor the instrument during use, which enables the generator to modulate and decrease its power output as well as provide audible feedback to the user as appropriate.

The HARMONIC FOCUS®+ Shears is designed for use exclusively with the Generator G11 (GEN11) software version 2013_1 or later and HARMONIC® Blue Hand Piece, packaged separately. Software revision can be found under “System Information” in the Generator G11 (GEN11) “Settings” Menu. Refer to the Generator G11 (GEN11) Operator’s Manual for more information.

Refer to the Instructions for Use of the HARMONIC Blue Hand Piece and Test Tip (TTBLUE) for instructions regarding the hand piece.

Illustration and Nomenclature (Illustration 1)

1. Torque Wrench
2. Blade
3. Clamp Arm and Tissue Pad
4. Handle Housing
5. Finger Rings
6. Finger Ring Rests
7. MIN Hand Control (proximal)
8. MAX Hand Control (distal)
9. Hand Piece (not included)

Transport and Storage Conditions

Temperature: -22°C to +60°C
Relative Humidity: 10–80%

Instructions for Use

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

The hand piece and test tip, packaged separately, are shipped non-sterile and must be sterilized per the insert instructions prior to each use.

Assembly

- 1 Using aseptic technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
- 2 While holding the hand piece, attach the instrument by rotating it onto the hand piece in a clockwise rotation as viewed from the distal end of the instrument (finger tight only) (Illustration 2).
- 3 Use the purple torque wrench to tighten the instrument onto the hand piece. Turn the wrench clockwise while holding the hand piece until it clicks twice, indicating that sufficient torque has been applied to secure the instrument (Illustration 3). In the event that the torque wrench must be re-positioned on

the instrument, ensure that the torque wrench is re-positioned correctly, as shown in Illustration 3. When properly aligned, the short side of the torque wrench should be aligned with the instrument hand controls, handle housing, and the Hand Piece, and the “Dispose of Properly” icon on the torque wrench should be on top. To ensure proper assembly, do not grip the instrument handle while applying torque with the Torque Wrench.

Caution: Do not torque the instrument by hand or damage may occur to the hand piece. Do not use any means other than the torque wrench to attach or detach the instrument from the hand piece.

- 4 Remove the torque wrench from the instrument. Do not discard the disposable torque wrench until the completion of the surgical case. The torque wrench is used for removal of the instrument from the hand piece following the procedure (Illustration 4). In the event the torque wrench falls out of the sterile field, replace with a sterile, purple torque wrench. Do not re-sterilize the disposable torque wrench.

Caution: Take care to avoid damage to the shears when removing the torque wrench from the instrument.

- 5 The second activation tone can be turned off under the “Settings” Menu on the G11 generator. See Generator G11 (GEN11) Operator’s Manual for more information.
 - This will deactivate the second activation tone only; this will not affect the Adaptive Tissue Technology’s modulation and decrease of power output.

Operation

Refer to a compatible HARMONIC Generator User Manual for hand piece attachment and system operation instructions.

- 1 Connect the assembled hand piece and instrument to the generator and turn the generator power on. Do not turn the generator power on before the hand piece and instrument are connected to the generator.
- 2 Select the desired variable or minimum power level using the INCREASE and DECREASE buttons on the generator.
 - Minimum starting power level defaults to power level 3 (Illustration 5). For greater tissue cutting speed use a higher generator power level, and for greater coagulation use a lower generator power level. The amount of energy delivered to the tissue and resultant tissue effects are a function of many factors, including the power level selected, blade characteristics, grip force, tissue tension, tissue type, pathology, and surgical technique.
 - MAX power is set at power level 5 and cannot be adjusted.
- 3 The HARMONIC FOCUS+ Long Shears instrument may be operated with either the foot switch or hand control. For foot switch or hand control function, refer to a compatible HARMONIC Generator User Manual for further detail and setup and operation instructions.
- 4 For optimal performance, clean the instrument blade and clamp arm throughout the procedure by activating the instrument tip in sterile saline (Illustration 6). The instrument can be wiped with a sterile moist gauze sponge to remove tissue, if necessary.

WARNING: Do not touch the instrument to metal while activated (Illustration 7). See **Warnings and Precautions.**
- 5 If tissue is still visible in the clamp arm, use hemostats to remove residue (Illustration 8).
- 6 The blade is ultrasonically energized when either the foot switch pedal is depressed or one of the hand controls is depressed.
 - Pressing either the left foot pedal of the foot switch or the proximal hand control (MIN) on the instrument activates the selected minimum power level.
 - Pressing either the right foot pedal of the foot switch or distal hand control (MAX) on the instrument activates the maximum power level.
 - The generator provides an audible tone to indicate when the instrument blade is active.
 - The generator changes to a second activation tone as Adaptive Tissue Technology regulates the delivery of energy.

- Thermal influences such as fluids or minimal to no tissue in the jaws may affect the presence or timing of the tone change.
- The tone change does not provide confirmation of tissue effect. When the second tone is heard, the situation should be assessed and the intended surgical action completed, such as gradual application of tension to facilitate transection.
- The secondary activation tone change is not a substitute for surgical experience.

WARNING: Avoid accidental contact with other instruments during use. Scratches on the blade may lead to premature blade failure.

- 7 Close the clamp arm and insert the instrument through the incision. Use the HARMONIC FOCUS+ Long Shears for dissection, grasping, coagulation, and cutting between the blade and clamp arm. Use the top of the blade with the jaws open if using for backcutting.

Caution: Do not use finger ring rests to extend reach during procedure, as this could result in poor vessel sealing and unstable positioning of the instrument (Illustration 9).

WARNING: Keep the jaws of the device open when backcutting or while the blade is active without tissue between the blade and tissue pad, to avoid damage to the tissue pad, and increased blade, clamp arm, and distal shaft temperatures.

Disassembly

- 1 Turn the generator **OFF** at the power switch.
- 2 Close the clamp arm and place the purple torque wrench over the distal end of the instrument.
- 3 While holding the hand piece, loosen the instrument by turning the torque wrench counterclockwise. Continue to loosen by turning the instrument manually to completely unscrew it from the hand piece.
- 4 Remove the torque wrench from the instrument. Dispose of the instrument and the torque wrench in an appropriate container.

How Supplied

The HARMONIC FOCUS+ Long Shears and purple torque wrench are supplied sterile for single patient use. Discard after use.

	<p>Relative Humidity Humidité relative Relative Feuchte Umidità relativa Humidade relativa Humedad relativa Relativ fugtighed Relativ fugtighed</p>	<p>Suhteellinen kosteus Σχετική υγρασία Relativ fuktighet Wilgotność względna Relatív páratartalom Relativní vlhkost Relatívna vlhkosť 相对湿度</p>
	<p>Temperature Température Temperatur Temperatura Temperatura Temperatura Temperatuur Temperatur</p>	<p>Lämpötila Θερμοκρασία Temperatur Temperatura Hőmérséklet Teplota Teplota 温度</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 χρήσης Se bruksanvisningen Patrz Instrukcja użytkowania Lásd a használati útmutatót Prostudujte návod k použití Prečítajte si návod na použitie 参见使用说明</p>



Do not use the HARMONIC FOCUS Long Shears with ULTRACISION® Generator (GEN01/GEN32/GEN04).

Ne pas utiliser les ciseaux HARMONIC FOCUS avec le générateur ULTRACISION® (GEN01/GEN32/GEN04).

Die HARMONIC FOCUS Schere darf nicht mit dem ULTRACISION® Generator (GEN01/GEN32/GEN04) eingesetzt werden.

Non usare la forbice HARMONIC FOCUS con il generatore ULTRACISION® (GEN01/GEN32/GEN04).

Não utilize a tesoura HARMONIC FOCUS com o Gerador ULTRACISION® (GEN01/GEN32/GEN04).

No utilice las tijeras HARMONIC FOCUS con el generador ULTRACISION® (GEN01/GEN32/GEN04).

Gebruik de HARMONIC FOCUS schaar niet met de ULTRACISION® generator (GEN01/GEN32/GEN04).

Brug ikke HARMONIC FOCUS saksen sammen med ULTRACISION® generatoren (GEN01/GEN32/GEN04).

HARMONIC FOCUS -saksia ei saa käyttää ULTRACISION®-generaattorin (GEN01/GEN32/GEN04) kanssa.

Μη χρησιμοποιείτε το ψαλίδι HARMONIC FOCUS με τη γεννήτρια ULTRACISION® (GEN01/GEN32/GEN04).

Använd inte HARMONIC FOCUS-saxen tillsammans med ULTRACISION®-generatoren (GEN01/GEN32/GEN04).

Nie wolno używać nożyc HARMONIC FOCUS z generatorem ULTRACISION® (GEN01/GEN32/GEN04).

A HARMONIC FOCUS metszőket tilos az ULTRACISION® generátorral (GEN01/GEN32/GEN04) használni!

Nůžky HARMONIC FOCUS nepoužívejte s generátorem ULTRACISION® (GEN01/GEN32/GEN04).

Nožnice HARMONIC FOCUS nepoužívajte s generátorom ULTRACISION® (GEN01/GEN32/GEN04).

HARMONIC FOCUS剪刀不能与ULTRACISION®发生器 (GEN01/GEN32/GEN04) 一起使用。

<p>For Use with BLUE Hand Piece ONLY</p>	<p>For use with Blue Hand Piece only.</p> <p>Utilisable uniquement avec une poignée de connexion Bleue.</p> <p>Nur für den Einsatz in Verbindung mit dem blauen Handstück.</p> <p>Da usarsi solo con il manipolo blu.</p> <p>Para ser utilizado apenas com a peça de mão azul.</p> <p>Para utilizar con el mango transductor azul únicamente.</p> <p>Uitsluitend voor gebruik met het blauwe handstuk.</p> <p>Kun til brug med det blå håndstykke.</p> <p>Tarkoitettu käytettäväksi ainoastaan sinisen kahvaosan kanssa.</p> <p>Για χρήση αποκλειστικά με την μπλε χειρολαβή.</p> <p>Endast för användning med blå kopplingsenhet.</p> <p>Do użytku wyłącznie z niebieską rączką.</p> <p>Kizárólag a kék kézidarabbal használható.</p> <p>Pouze pro použití s modrým nástavcem.</p> <p>Iba na použitie s modrou rukoväťou.</p> <p>只可与蓝色手柄配合使用。</p>
	<p>Dispose of properly.</p> <p>Éliminer de façon appropriée.</p> <p>Ordnungsgemäß entsorgen.</p> <p>Eliminare a norma.</p> <p>Elimine correctamente.</p> <p>Desechar adecuadamente.</p> <p>Op de geschikte wijze afvoeren.</p> <p>Bortskaffes på korrekt vis.</p> <p>Hävitä asianmukaisesti.</p> <p>Απορρίψτε με τον ενδεδειγμένο τρόπο.</p> <p>Kassera på lämpligt sätt.</p> <p>Usunąć w odpowiedni sposób.</p> <p>Megfelelő módon helyezze hulladékba.</p> <p>Zlikvidujte předepsaným způsobem.</p> <p>Riadne zlikvidujte.</p> <p>妥善废弃。</p>

<p>STERILE EO</p>	<p>Sterilized by Ethylene Oxide Stérilisé à l'oxyde d'éthylène. Stérilité garantie si l'emballage n'a pas été ouvert ou endommagé. Ne pas restériliser. EO-sterilisiert. Nicht verwenden, wenn die Sterilverpackung geöffnet oder beschädigt ist. Nicht reesterilisieren. Sterilizzato ad ossido di etilene. Sterilità garantita, a meno che la confezione non venga aperta o danneggiata. Non risterilizzare. Esterilização por óxido de etileno. Esterilização garantida excepto se a embalagem estiver aberta ou danificada. Não reesterilizar. Esterilizado por óxido de etileno. Esterilización garantizada mientras el envase esté íntegro. No reesterilizar. Gesteriliseerd met ethyleenoxide. Steriliteit gegarandeerd tenzij de verpakking is geopend of beschadigd. Niet opnieuw steriliseren. Steriliserede med ethylenoxid. Garanteret sterilt, med mindre pakken er åbnet eller beskadiget. Må ikke gensteriliseres. Steriloitu etyleenioksidilla. Tuote on steriili, kun pakkaus on avaamaton ja ehjä. Ei saa steriloida uudestaan. Αποστειρωμένα με αιθυλενοξειδίο. Η στειρότητα είναι εγγυημένη εφόσον δεν ανοιχθεί η συσκευασία ή δεν προκληθεί ζημιά σε αυτήν. Μην επαναποστειρώνετε. Steriliserade med etylenoxid. Steriliteten garanteras under förutsättning att förpackningen inte är öppnad eller skadad. Får ej omsteriliseras. Produkt sterylizowany tlenkiem etylenu. Jałowość gwarantowana pod warunkiem, że opakowanie nie zostało otwarte lub uszkodzone. Nie sterylizować ponownie. Etilén-oxiddal sterilizálva. A sterilitása addig garantálható, amíg ki nem nyitják, illetve meg nem sérül a csomagolás. Tilos újra sterilizálni. Sterilizováno etylenoxidem. Sterilnost je zaručena, pokud balení není otevřené nebo poškozené. Nástroj znovu nesterilizujte. Sterilizované etylén oxidom. Sterilita je zarucená, ak nie je otvorený alebo poškodený obal. Neresterilizujte. 环氧乙烷灭菌。 如果产品包装未开封或者未破损，保证无菌。不得再次灭菌。</p>
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	<p>Do Not Resterilize Do Not Resterilize</p>
	<p>Do Not Use if Package is Damaged. Do Not Use if Package is Damaged.</p>

	<p>Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.</p> <p>Mise en garde : la loi fédérale (États-Unis d'Amérique) n'autorise la vente de ce dispositif que par un médecin ou sur sa prescription.</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>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>Authorized Representative in the USA</p> <p>Représentant autorisé aux États-Unis d'Amérique</p> <p>Bevollmächtigter in den USA</p> <p>Rappresentante autorizzato per gli Stati Uniti</p> <p>Representante autorizado nos EUA</p> <p>Representante autorizado en EE.UU.</p> <p>Bevoegd vertegenwoordiger in de VS</p> <p>Bemyndiget repræsentant i USA</p> <p>Valtuutettu edustaja Yhdysvalloissa</p> <p>Εξουσιοδοτημένος αντιπρόσωπος στις ΗΠΑ</p> <p>Auktoriserad representant i USA</p> <p>Autoryzowany przedstawiciel w Stanach Zjednoczonych Ameryki</p> <p>Meghatalmazott képviselő az Egyesült Államokban</p> <p>Autorizovaný zástupce v USA</p> <p>Autorizovaný zástupca v USA</p> <p>美国授权代理人</p>

	<p>Authorized Representative in the European Community Représentant autorisé dans la Communauté européenne Bevollmächtigter in der Europäischen Gemeinschaft Rappresentante autorizzato nella 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 欧共同体内授权代理</p>
	<p>Manufacturer financially contributes to the cost of recovery and recycling. Le fabricant contribue financièrement au coût de la récupération et du recyclage. (Selon réglementation nationale locale, le cas échéant). Hersteller beteiligt sich finanziell an den Sammel- und Recycling-Kosten. Il fabbricante contribuisce finanziariamente al costo del recupero e del riciclo. O fabricante contribui financeiramente para o custo de recuperação e reciclagem. El fabricante contribuye económicamente al coste de recuperación y reciclaje. De fabrikant draagt financieel bij in de kosten van herstel en recycling Producenten dækker omkostningerne til genvinding og genbrug. Valmistaja osallistuu palautus- ja kierrätyskulujen rahoitukseen. Ο κατασκευαστής συνεισφέρει οικονομικά στο κόστος ανάκτησης και ανακύκλωσης. Tillverkaren ger finansiellt bidrag till kostnaden för återvinning och återanvändning. Wytwórca finansowo przyczynia się do pokrycia kosztu odzyskania i recyklingu produktu. A gyártó pénzügyileg hozzájárul a regenerálási és újrahasznosítási költségekhez. Výrobce finančně prispívá k nákladům na obnovu a recyklaci. Výrobca finančne prispieva na náklady na vrátenie a recykláciu. 制造商在经济上支持废物回收和再利用。</p>

1

Unit Quantity
Unit Quantity

REF
HAR17F

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ETHICON

PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES



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Rev. 2014-XX-XX

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Instructions for Use – HAR9F

ETHICON

HARMONIC FOCUS® Shears + Adaptive Tissue Technology
Ciseaux HARMONIC FOCUS® + Technologie Tissulaire Adaptive
HARMONIC FOCUS® Koagulationsschere + Adaptive Tissue Technology
Forbici HARMONIC FOCUS® + tecnologia adattativa al tessuto
Tesoura HARMONIC FOCUS® + Tecnologia Tecidual Adaptável
Cizallas HARMONIC FOCUS® + Tecnología adaptativa tisular
HARMONIC FOCUS®-schaar + adaptieve weefseltechnologie
HARMONIC FOCUS® saks + adaptiv vævsteknologi
HARMONIC FOCUS® -saket + mukautuva kudostekniikka
Ψαλίδι HARMONIC FOCUS® + Προσαρμοζόμενη τεχνολογία ιστού
HARMONIC FOCUS® sax + adaptiv vävnadsteknologi
Nożyce HARMONIC FOCUS® + adaptacyjna technologia tkankowa
HARMONIC FOCUS® metsző + adaptiv szövetechnológia
Nůžky HARMONIC FOCUS® + s adaptivní tkáňovou technologií
Nožnice HARMONIC FOCUS® + s adaptivnou tkanivovou technológiou
HARMONIC FOCUS® skjærere + adaptiv vevs-tekologi
HARMONIC FOCUS® Makas + Adaptif Doku Teknolojisi
Ножницы с технологией адаптации к тканям HARMONIC FOCUS®
Pensă foarfecă HARMONIC FOCUS® + tehnologia de adaptare la țesut
Gunting HARMONIC FOCUS® + Teknologi Jaringan Adaptif
Kéo HARMONIC FOCUS® + Công nghệ Mô thích ứng
HARMONIC Focus® 多用剪 + 自适应组织技术



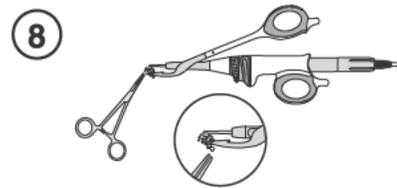
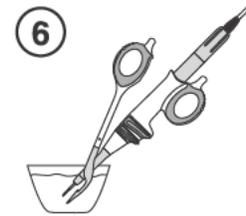
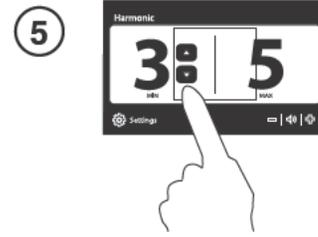
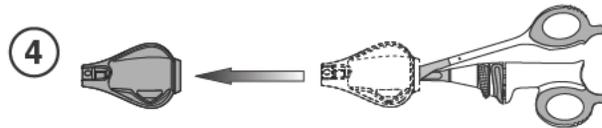
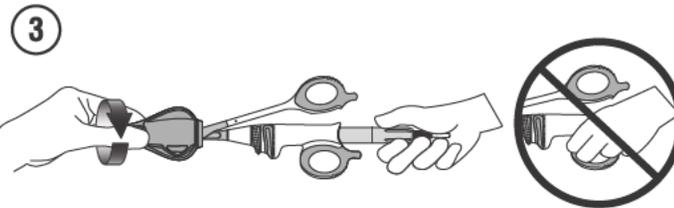
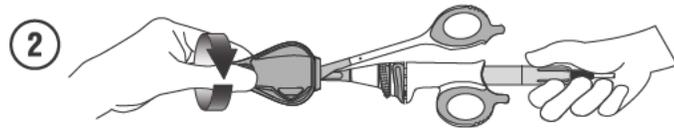
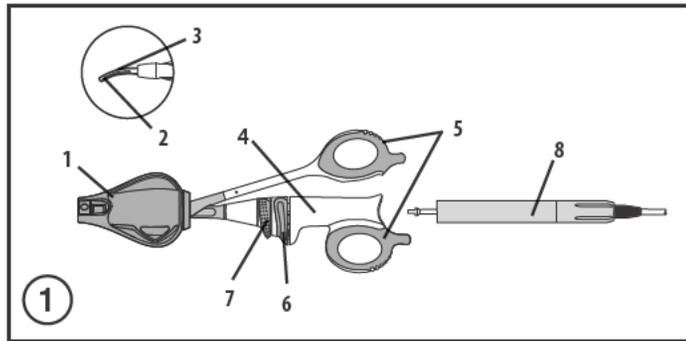
Please read all information carefully.

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 HARMONIC FOCUS® Shears + Adaptive Tissue Technology. It is not a reference to ligation techniques.

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Instructions, Instrucciones, Gebrauchsanweisung, Istruzioni, Instruções, Instrucciones,
Gebruiksaanwijzing, Brugsvejledning, Ohje, Οδηγίες, Bruksanvisning, Instrukcja,
Utastítások, Návod k použití, Návod, Instrukcije, Talimatlar, инструкции, Instrucțiuni,
Instruksi, Hướng dẫn, 使用说明



Indications

The HARMONIC FOCUS® SHEARS + ADAPTIVE TISSUE TECHNOLOGY are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, otorhinolaryngologic (ENT), plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open procedures.

Contraindications

- The instrument is not indicated for incising bone
- The instrument is not intended for contraceptive tubal occlusion

Warnings and Precautions

- Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
- 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 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 instruments in liquid unless the instruments are designed and labeled to be immersed
- Verify compatibility with generators. HARMONIC FOCUS®+ Shears are compatible only with Ethicon Endo-Surgery Generator G11 (GEN11) software version 2013.1 or later. Software revision can be found under "System Information" in the Generator G11 (GEN11) "Settings" Menu. Refer to the Generator G11 (GEN11) Operator's Manual for more information
- Audible high-pitched ringing, resonating from the blade or Hand Piece, are an abnormal condition and an indicator that the blade or Hand Piece is not operating properly. The ringing may be an indicator that the Hand Piece is beyond its useful life or that the blade has not been attached properly, which may result in abnormally high shaft temperatures and user or patient injury
- In case of system failure, ensure the availability of the appropriate back-up equipment relevant to the specific procedure
- Blood and tissue buildup between the blade and shaft may result in abnormally high temperatures at the distal end of the shaft. To prevent burn injury, remove any visible tissue buildup at the distal end of the shaft
- As with all energy sources (Electrosurgery, Laser, or Ultrasound), there are concerns about the carcinogenic and infectious potential of the by-products, such as tissue smoke plume and aerosols. Appropriate measures such as protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures
- Do not attempt to bend, sharpen, or otherwise alter the shape of the blade. Doing so may cause blade failure and user or patient injury
- To avoid user or patient injury in the event that accidental activation occurs, the instrument blade, clamp arm, and distal end of the shaft should not be in contact with the patient, drapes, or flammable materials while not in use
- During and following activation in tissue, the instrument blade and clamp arm may become hot. Avoid unintended contact with tissue, drapes, surgical gowns, or other unintended sites at all times
- Incidental and prolonged activation against solid surfaces, such as bone, may result in blade heating and subsequent blade failure, and should be avoided

- Avoid contact with any and all metal or plastic instruments or objects when the instrument is activated. Contact with staples, clips, or other instruments while the instrument is activated may result in cracked or broken blades, which may be identified by generator solid tone or instrument error
- Scratches on the blade may lead to premature blade failure
- Care should be taken not to apply pressure between the instrument blade and tissue pad without having tissue between them. Clamping the tissue pad against the active blade without tissue on the full length of the blade will result in higher blade, clamp arm and distal shaft temperatures and can result in possible damage to the instrument. If this happens, there may be a system failure signaled by a continuous tone or alert screen when either of the foot pedals or hand control buttons is depressed
- Keep the jaws of the device open when backcutting or while the blade is active without tissue between the blade and tissue pad to avoid damage to the tissue pad and increased blade, clamp arm, and distal shaft temperatures
- To avoid user or patient injury, do not activate an electrosurgical device in close proximity to the HARMONIC instruments. The aerosols created by the activation of the HARMONIC instruments in fatty tissue are potentially flammable
- The entire exposed blade tip and any exposed blade shaft is active and will cut/coagulate tissue when the HARMONIC FOCUS®+ Shears blade is activated. Be careful to avoid inadvertent contact between all exposed blade surfaces and surrounding tissue when using the HARMONIC FOCUS + instrument
- Use only the HARMONIC Foot Switch, and the Blue Hand Piece, with the FOCUS + instrument to ensure compatibility with the Generator
- After removing the instrument, examine the tissue for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis
- The sealing performance of this instrument has not been assessed on atherosclerotic vessels. Exercise caution when transecting these vessels as they may not seal properly
- Minimum starting power level defaults to power level 3
- Successful hemostasis may require adjunct measures when HARMONIC FOCUS®+ Shears instruments are used on solid organs. Due to the difficulty of visualizing internal structures, proceed slowly and do not attempt to transect large masses of tissue in one activation. Avoid the division of large vascular/biliary bundles when using the HARMONIC FOCUS®+ Shears instrument under these conditions
- Products manufactured or distributed by companies not authorized by Ethicon Endo-Surgery may not be compatible with the HARMONIC FOCUS®+ Shears instrument. Use of such products may lead to unanticipated results and possible injury to the user or patient
- Do not torque the instrument by hand or damage may occur to the Hand Piece. Do not use any means other than the Torque Wrench to attach or detach the instrument from the Hand Piece
- Take care to avoid damage to the shears when removing the Torque Wrench from the instrument
- Do not clean the instrument with abrasives
- 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. Multiple patient use may compromise the device integrity or create a risk of contamination that, in turn, may result in patient injury or illness

Device Description

The HARMONIC FOCUS®+ Shears is a sterile, single patient use instrument consisting of a soft grip scissor handle housing assembly with two hand controls (MIN for minimum power level and MAX for maximum power level). The instrument has a curved blade and clamp arm with teflon pad. The instrument is 9 cm in length with a 16 mm active blade length. The HARMONIC FOCUS®+ Shears instrument allows for the cutting and coagulation of vessels up to and including 5 mm in diameter.

Each HARMONIC FOCUS®+ Shears instrument is packaged with one sterile, single patient use, disposable Gray Torque Wrench. Use only the Gray Torque Wrench with the HARMONIC FOCUS®+ Shears instrument.

The torque wrench should not be discarded until the completion of the surgical case. Do not attempt to sterilize the disposable torque wrench.

The two dashes on the instrument are intended to represent relative vessel size. The MAX (☐) button is typically used for smaller vessels where cutting speed is fastest. The MIN (☐) button is typically used in slightly larger vessels and has reduced cutting speed. It is indicated for vessels up to 5 mm in size. Adaptive Tissue Technology provides the generator with the ability to identify and monitor the instrument during use, which enables the generator to modulate and decrease its power output as well as provide audible feedback to the user as appropriate.

The HARMONIC FOCUS[®]+ Shears is designed for use exclusively with the Generator G11 (GEN11) software version 2013.1 or later and HARMONIC Blue Hand Piece, packaged separately. Software revision can be found under "System Information" in the Generator G11 (GEN11) "Settings" Menu. Refer to the Generator G11 (GEN11) Operator's Manual for more information.

Refer to the Instructions for Use of the Harmonic Blue Hand Piece and Test Tip (TTBLUE) for instructions regarding the Hand Piece.

Illustration and Nomenclature (Illustration 1)

1. Torque Wrench
2. Blade
3. Clamp Arm and Tissue Pad
4. Handle Housing
5. Finger Rings
6. MIN Hand Control (proximal)
7. MAX Hand Control (distal)
8. Hand Piece (not included)

Transport and Storage Conditions

Temperature: -22°C to +60°C
Relative Humidity: 10-80%

Instructions for Use

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

The Hand Piece and Test Tip, packaged separately, are shipped non-sterile and must be sterilized per the insert instructions prior to each use.

Assembly

1. Using aseptic technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
2. While holding the Hand Piece, attach the instrument by rotating it onto the Hand Piece in a clockwise rotation as viewed from the distal end of the instrument (finger tight only) (Illustration 2).
3. Use the Gray Torque Wrench to tighten the instrument onto the Hand Piece. Turn the wrench clockwise while holding the Hand Piece until it clicks twice, indicating that sufficient torque has been applied to secure the instrument (Illustration 3). To ensure proper assembly, do not grip the instrument handle while applying torque with the Torque Wrench.
Caution: Do not torque the instrument by hand or damage may occur to the Hand Piece. Do not use any means other than the Torque Wrench to attach or detach the instrument from the Hand Piece.
4. Remove the Torque Wrench from the instrument. Do not discard the disposable Torque Wrench until the completion of the surgical case. The Torque Wrench is used for removal of the instrument from the Hand Piece following the procedure (Illustration 4). In the event the Torque Wrench falls out of

the sterile field, replace with a sterile Gray Torque Wrench. Do not re-sterilize the disposable Torque Wrench.

Caution: Take care to avoid damage to the shears when removing the Torque Wrench from the instrument.

5. The second activation tone can be turned off under the "Settings" Menu on the G11 generator. See Generator G11 (GEN11) Operator's Manual for more information.
 - This will deactivate the second activation tone only; this will not affect the Adaptive Tissue Technology's modulation and decrease of power output.

Operation

Refer to a compatible HARMONIC Generator User Manual for hand piece attachment and system operation instructions.

1. Connect the assembled Hand Piece and instrument to the generator and turn the generator power on. Do not turn the generator power on before the Hand Piece and instrument are connected to the generator.
 2. Select the desired variable or minimum power level using the INCREASE and DECREASE buttons on the generator.
 - Minimum starting power level defaults to power level 3 (Illustration 5). For greater tissue cutting speed use a higher generator power level, and for greater coagulation use a lower generator power level. The amount of energy delivered to the tissue and resultant tissue effects are a function of many factors, including the power level selected, blade characteristics, grip force, tissue tension, tissue type, pathology, and surgical technique.
 - MAX power is set at power level 5 and cannot be adjusted.
 3. The HARMONIC FOCUS[®]+ Shears instrument may be operated with either the foot switch or hand control. For foot switch or hand control function, refer to a compatible HARMONIC Generator User Manual for further detail and setup and operation instructions.
 4. For optimal performance, clean the instrument blade and clamp arm throughout the procedure by activating the instrument tip in sterile saline (Illustration 6). The instrument can be wiped with a sterile moist gauze sponge to remove tissue, if necessary.
WARNING: Do not touch the instrument to metal while activated (Illustration 7). See **Warnings and Precautions**.
 5. If tissue is still visible in the clamp arm, use hemostats to remove residue (Illustration 8).
 6. The blade is ultrasonically energized when either the foot switch pedal is depressed or one of the hand controls is depressed.
 - Pressing either the left foot pedal of the foot switch or the proximal hand control (MIN) on the instrument activates the selected minimum power level.
 - Pressing either the right foot pedal of the foot switch or distal hand control (MAX) on the instrument activates the maximum power level.
 - The generator provides an audible tone to indicate when the instrument blade is active.
 - The generator changes to a second activation tone as Adaptive Tissue Technology regulates the delivery of energy.
 - Thermal influences such as fluids or minimal to no tissue in the jaws may affect the presence or timing of the tone change.
 - The tone change does not provide confirmation of tissue effect. When the second tone is heard, the situation should be assessed and the intended surgical action completed, such as gradual application of tension to facilitate transection.
 - The secondary activation tone change is not a substitute for surgical experience.
- WARNING:** Avoid accidental contact with other instruments during use. Scratches on the blade may lead to premature blade failure. See **Warnings and Precautions**.

- 7 Close the clamp arm and insert the instrument through the incision. Use the HARMONIC FOCUS*+ Shears for dissection, grasping, coagulation, and cutting between the blade and clamp arm. Use the top of the blade with the clamp arm open if using for backcutting.
WARNING: Keep the clamp arm open when backcutting or while the blade is active, without tissue between the blade and tissue pad, to avoid damage to the tissue pad.

Disassembly

- 1 Turn the generator OFF at the power switch
- 2 Close the clamp arm and place the Gray Torque Wrench over the distal end of the instrument
- 3 While holding the Hand Piece, loosen the instrument by turning the Torque Wrench counterclockwise. Continue to loosen by turning the instrument manually to completely unscrew it from the Hand Piece
- 4 Remove the Torque Wrench from the instrument. Dispose of the instrument and the Torque Wrench in an appropriate container

How Supplied

The HARMONIC FOCUS* + Shears and Gray Torque Wrench are supplied sterile for single patient use. Discard after use.

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	<p>See Instructions For Use (Refer to blue symbol on outer packaging) Voir la notice d'utilisation (se reporter au symbole bleu sur l'emballage extérieur) Bitte Gebrauchsanweisung beachten (siehe blaues Symbol an der äußeren Verpackung) Vedere le Istruzioni per l'uso (vedere il simbolo blu sulla confezione esterna) Consulte as Instruções de utilização (consulte o símbolo azul na embalagem exterior) Ver instrucciones de uso (refiérase al símbolo azul en el envase exterior) Zie de gebruiksaanwijzing (zie het blauwe symbool op de buitenste verpakking) Se betjeningsvejledning (der henviser til det blå symbol på yderemballagen) Katso käyttöohjeita (katso sinistä symbolia ulkopakkauksessa) Δείτε τις Οδηγίες Χρήσης (ανατρέξτε στο μπλε σύμβολο, στο εξωτερικό της συσκευασίας) Se bruksanvisningen (se den blå symbolen på yttre förpackningen) Należy zapoznać się z instrukcją użytkowania (patrz niebieski symbol na zewnętrznych opakowaniach) Lásd a használati útmutatót (lásd a kék szímszimbólumot) Viz návod k použití (informace jsou uvedeny u modrého symbolu na vnějším balení) Prečítajte si návod na použitie (vzťahuje sa na modrý symbol na vonkajšom obale) Se Bruksanvisning (se det blå symbolet på ytteremballasjen) Kullanım Talimatları'na bakın (Dış ambalaj üzerindeki mavi sembole başvurun.) См инструкцию по применению (См синий символ на внешней упаковке) Consultați instrucțiunile de utilizare (faceți referire la simbolul albastru de pe ambalajul exterior) Lihat Instruksi Penggunaan (Lihat simbol berwarna biru di bagian luar kemasan) Xem Hướng dẫn sử dụng (tham khảo biểu tượng xanh dương trên bao bì bên ngoài) 参见使用说明 (请参阅外包装上的蓝色符号)。</p>	
	<p>Relative Humidity Humidité relative Relative Feuchte Umidità relativa Humidade relativa Humedad relativa Relativ fugtighed Relativ fugtighed Suhteellinen kosteus Συγκριτική υγρασία Relativ fuktighet</p>	<p>Wilgotność względna Relativ páratartalom Relativni vlhkost Relativna vlhkost Relativ luftfuktighet Bağıl Nem Относительная влажность Umiditate relativă Kelembapan Relatif Độ ẩm tương đối 相对湿度</p>
	<p>Temperature Température Temperatur Temperatura Temperatura Temperatur Temperatur Temperatur Temperatur Lampótia Θερμοκρασία Temperatur</p>	<p>Temperatura Hőmérséklet Teplota Teplota Temperatur Sıcaklık Температуры Temperatură Suhu Nhiệt độ 溫度</p>

	<p>Do not use the HARMONIC FOCUS Shears with ULTRACISION® Generator (GEN01/GEN32/GEN04/GEN04) Ne pas utiliser les ciseaux HARMONIC FOCUS avec le générateur ULTRACISION® (GEN01/GEN32/GEN04) Die HARMONIC FOCUS Schere darf nicht mit dem ULTRACISION® Generator (GEN01/GEN32/GEN04) eingesetzt werden Non usare la forbice HARMONIC FOCUS con il generatore ULTRACISION® (GEN01/GEN32/GEN04) Não utilize a tesoura HARMONIC FOCUS com o Gerador ULTRACISION® (GEN01/GEN32/GEN04) No utilize las tijeras HARMONIC FOCUS con el generador ULTRACISION® (GEN01/GEN32/GEN04) Gebruik de HARMONIC FOCUS schaar niet met de ULTRACISION® generator (GEN01/GEN32/GEN04) Brug ikke HARMONIC FOCUS saksen sammen med ULTRACISION® generatoren (GEN01/GEN32/GEN04) HARMONIC FOCUS -saksia ei saa käyttää ULTRACISION®-generaattorin (GEN01/GEN32/GEN04) kanssa Μη χρησιμοποιείτε το ψαλίδι HARMONIC FOCUS με τη γεννήτρια ULTRACISION® (GEN01/GEN32/GEN04) Använd inte HARMONIC FOCUS-saxen tillsammans med ULTRACISION®-generatorm (GEN01/GEN32/GEN04) Nie wolno używać nożyce HARMONIC FOCUS z generatorem ULTRACISION® (GEN01/GEN32/GEN04) A HARMONIC FOCUS metszőket tilos az ULTRACISION® generátorral (GEN01/GEN32/GEN04) használni! Nůžky HARMONIC FOCUS nepoužívejte s generátorem ULTRACISION® (GEN01/GEN32/GEN04) Nožnice HARMONIC FOCUS nepoužívajte s generátorom ULTRACISION® (GEN01/GEN32/GEN04) Ikke bruk HARMONIC FOCUS skjærere med ULTRACISION® Generator (GEN01/GEN32/GEN04/GEN04) HARMONIC FOCUS Makası ULTRACISION® Jeneratör (GEN01/GEN32/GEN04/GEN04) ile kullanmayın Запрещается использовать ножницы HARMONIC FOCUS с генератором ULTRACISION® (GEN01/GEN32/GEN04/GEN04) Nu utilizați pensa foarfecă HARMONIC FOCUS cu generatorul ULTRACISION® (GEN01/GEN32/GEN04/GEN04) Jangan gunakan Gunting HARMONIC FOCUS dengan Generator ULTRACISION® (GEN01/GEN32/GEN04/GEN04) Không được sử dụng Kéo HARMONIC FOCUS với Máy phát ULTRACISION® (GEN01/GEN32/GEN04/GEN04) HARMONIC FOCUS 剪刀不能与 ULTRACISION® 发生器 (GEN01/GEN32/GEN04) 一起使用。</p>
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<p>For Use with BLUE Hand Piece ONLY</p>	<p>For use with Blue Hand Piece only Utilisable uniquement avec une poignée de connexion Bleue Nur für den Einsatz in Verbindung mit dem blauen Handstück Da usarsi solo con il manipolo blu Para ser utilizado apenas com a peça de mão azul Para utilizar con el mango transductor azul únicamente Uitsluitend voor gebruik met het blauwe handstuk Kun til brug med det blå håndstykke Tarkoitettu käytettäväksi ainoastaan sinisen kahvaosan kanssa Για χρήση αποκλειστικά με την μπλε χειρολαβή Endast för användning med blå kopplingsenhet Do użytku wyłącznie z niebieską rączką Kizárólag a kék kézidarabbal használható Pouze pro použití s modrým nástavcem Iba na použitie s modrou rukoväťou Kun for bruk med det blå håndstykket Sadece Mavi El Cihazı ile kullanılm içindir Использовать только с голубым ручным блоком A se utiliza numai cu piesa albastră de mână Untuk digunakan hanya dengan Pemegang Biru Chi sử dụng với Tay khoan xanh đúng 只可与蓝色手柄配合使用。</p>
	<p>Dispose of properly Eliminer de façon appropriée Ordnungsgemäß entsorgen Eliminare a norma Elimine correctamente Desechar adecuadamente Op de geschikte wijze afvoeren Bortskaffes på korrekt vis Hävita asianmukaisesti Απορρίψτε με τον ενδεδειγμένο τρόπο Kassera på lämpligt sätt Usunąć w odpowiedni sposób Megfelelő módon helyezze hulladékba Zlikvidujte předepsaným způsobem Riadne zlikvidujte Kasser på riktig måte Doğru şekilde imha edin Утилизировать надлежащим образом A se elimina corespunzător Hanya untuk sekali pakai Thải bỏ đúng quy định 妥善废弃。</p>

<p>STERILE EO</p>	<p>Sterilized by EO Sterility Guaranteed Unless Package Opened or Damaged Do Not Resterilize Stérilisé à l'oxyde d'éthylène Sterilità garantita si l'emballage n'a pas été ouvert ou endommagé Ne pas restériliser EO-sterilisiert Nicht verwenden, wenn die Sterilverpackung geöffnet oder beschädigt ist Nicht reesterilisieren Sterilizzato ad ossido di etilene Sterilità garantita, a meno che la confezione non venga aperta o danneggiata Non nsterilizare Esterilização por óxido de etileno Esterilização garantida excepto se a embalagem estiver aberta ou danificada Não reesterilizar Esterilizado por óxido de etileno Esterilización garantizada mientras el envase esté íntegro No reesterilizar Gesteriliseerd met ethyleenoxide Steriliteit gegarandeerd tenzij de verpakking is geopend of beschadigd Niet opnieuw steriliseren Steriliserede med ethylenoxid Garanteret steril, med mindre pakken er åbnet eller beskadiget Må ikke gensteriliseres Steriloitu etyleenioksidilla Tuote on steriili, kun pakkaus on avaamaton ja ehjä Ei saa steriloida uudestaan Αποστειρωμένα με αιθυλενοξείδιο Η στεριότητα είναι εγγυημένη εφόσον δεν ανοιχθεί η συσκευασία ή δεν προκληθεί ζημιά σε αυτήν Μην επανοστειρώνετε Steriliserade med etylenoxid Steriliteten garanteras under förutsättning att förpackningen inte är öppnad eller skadad Får ej omsteriliseras Produkt sterylizowany dzięki etylenowi Jalowość gwarantowana pod warunkiem, że opakowanie nie zostało otwarte lub uszkodzone Nie sterylizować ponownie Etilén-oxidál sterilizálva A sterilitása addig garantálható, amíg ki nem nyitják, illetve meg nem sérül a csomagolás Tilos újra sterilizálni Sterilizováno etylenoxidem Sterilnost je zaručena, pokud balení není otevřené nebo poškozené Nástroj znovu nesterilizujte Sterilizované etylén oxidom Sterilita je zaručená, ak nie je otvorený alebo poškodený obal Neresterilizujte Sterilisert med EO Steriliteten garanteres hvis ikke pakken er åpnet eller skadet Ikke sterilisert på nytt EO ile sterilize edilmistir Ambalaj açılmadıkça veya hasar görmedikçe sterillik garanti altındadır Стерилизовано этиленоксидом Стерильность гарантирована только при не вскрытой и неповрежденной упаковке Sterilizat cu oxid de etilenă (EO) Sterilitatea este garantată numai dacă ambalajul nu a fost desfăcut sau nu este deteriorat Nu reesterilizați Distenlisasi oleh EO Dijamin Steril Kecuali Jika Kemasan Terbuka atau Rusak Jangan Disteril Ulang Được khử trùng theo EO Bảo đảm khử trùng trừ khi gói sản phẩm bị mở hoặc hư hỏng Không được khử trùng lại 环氧乙烷灭菌。 如果产品包装未开封或者未破损, 保证无菌。不得再次灭菌。</p>
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	<p>Single Patient Use À utiliser sur un seul patient lors d'une seule et même intervention 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 Potilaskoitainen Χρήση σε έναν μόνον ασθενή</p>	<p>Endast för en patients bruk Do użytku u jednego pacjenta Egyetlen betegnél használható fel Nástroj je určený pouzre pro jednoho pacienta Určeno iba pre jedného pacienta For bruk på kun én pasient Tek Hastada Kullamm İçindir Использовать только для одного пациента Se utilizează pentru un singur pacient Digunakan Pada Pasien Tunggal Chi một bệnh nhân sử dụng 单个患者使用</p>
	<p>Lot N° de lot Ch -B Lotto N° do lote N° de lote Lotnr Parti Erän koodi Αρ παρτίδας Batchnummer</p>	<p>Numer partii producşynej Tétel Şarţe Sarza Serie Lot Партия Lot Lot Lot Lô 批号</p>
	<p>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</p>	<p>Koniec okresu przydatności do użytku A feltüntetett dátumig használható fel Použit do data Použitelné do Bruk til dato Son Kullanna Tarihi Использовать до A se utiliza de preferinţă înainte de data Batas Tanggal Penggunaan Được sử dụng đến ngày 有效期</p>
	<p>Manufacturer/Date of Manufacture Fabricant/Date de fabrication Hersteller/Datum der Herstellung Fabricante/Data di fabbricazione Fabricante/Fecha de fabricación Fabricante/Data de fabrico Fabrikant/productiedatum Producent/Fremstillingsdato Valmistaja/valmistuspäivä Κατασκευαστής/Ημερομηνία κατασκευής Tillverkare/Tillverkningsdatum</p>	<p>Producent/Data producşy Gyártó/Gyártás ideje Výrobce/Datum výroby Výrobca/Dátum výroby Producent/Produkşjonsdato Üretici/Üretim Tarihi Произвоитель/Дата производства Producător/Data fabricaţiei Pabrikant/Tanggal Produksi Nhà sản xuất/Ngày sản xuất 制造商/制造日期</p>

	<p>Authorized Representative in the European Community Représentant autorisé dans la Communauté européenne Bevollmächtigter in der Europäischen Gemeinschaft Rappresentante autorizzato nella 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 Valutettu 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 Autorisert representant i EU Авторизованный представитель в ЕС Reprezentant autorizat în Comunitatea Europeană Perwakilan Resmi di Negara Eropa Đại diện được ủy quyền tại Cộng đồng Châu Âu 欧共同体内授权代理</p>
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	<p>Caution: Federal (USA) law restricts this device to sale by or on the order of a physician</p> <p>Mise en garde : la loi fédérale (États-Unis d'Amérique) n'autorise la vente de ce dispositif que par un médecin ou sur sa prescription</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>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 lääkäriin 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>Przeostroga: 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>Forsiktig: Federal lov i USA begrenser salg av dette utstyret til salg av eller etter ordre fra en lege</p> <p>Dikkat: Federal (ABD) yasalar bu cihazın bir hekim tarafından veya hekim siparişiyle satılmasını zorunlu tutar</p> <p>Внимание! Согласно федеральному законодательству США, продажа этого изделия может осуществляться только врачом или по назначению врача</p> <p>Precauție: Legea federală (SUA) autorizează vânzarea acestui dispozitiv numai de către un medic sau la recomandarea acestuia</p> <p>Caution: Federal (USA) law restricts this device to sale by or on the order of a physician</p> <p>THẬN TRỌNG – Luật liên bang (Hoa Kỳ) chỉ cho phép bác sĩ được bán hoặc đặt hàng thiết bị này</p> <p>注意: 联邦 (美国) 法律只允许医师销售或订购该器械。</p>
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	<p>Authorized Representative in the USA</p> <p>Représentant autorisé aux États-Unis d'Amérique</p> <p>Bevollmächtigter in den USA</p> <p>Rappresentante autorizzato per gli Stati Uniti</p> <p>Representante autorizado nos EUA</p> <p>Representante autorizado en EE UU</p> <p>Bevoegd vertegenwoordiger in de VS</p> <p>Bemyndiget repræsentant i USA</p> <p>Valtuutettu edustaja Yhdysvalloissa</p> <p>Εξουσιοδοτημένος αντιπρόσωπος στις ΗΠΑ</p> <p>Auktoriserad representant i USA</p> <p>Autorizowany przedstawiciel w Stanach Zjednoczonych Ameryki</p> <p>Meghatalmazott képviselő az Egyesült Államokban</p> <p>Autorizovaný zástupce v USA</p> <p>Autorizovaný zástupca v USA</p> <p>Autorisert representant i USA</p> <p>ABD'deki Yetkili Temsilci</p> <p>Авторизованный представитель в США</p> <p>Reprezentant autorizat în SUA</p> <p>Authorized Representative in the USA</p> <p>Đại diện được ủy quyền tại Hoa Kỳ</p> <p>美国授权代理人</p>
---	--



REF
HAR9F



Ethicon Endo-Surgery (Europe) GmbH
Hummelsbuetteler Steindamm 71
22851 Norderstedt
GERMANY



ETHICON ENDO-SURGERY, INC.
4545 Creek Road
Cincinnati, OH 45242-2839 USA
1-877-ETHICON

ETHICON



ETHICON ENDO-SURGERY, LLC ©EES, LLC 2014
475 Calle C
Guaynabo, PR 00969 USA

Rev. 2014-02



0123
P40730P01

Ethicon Endo-Surgery, LLC
510(k) Premarket Notification (Special)

HARMONIC FOCUS® Long Shears + Adaptive Tissue Technology

Section 11: Declaration of Conformity with Design Controls

Declaration of Conformity: Verification Activities

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modifications were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.



Stephanie Matthews
Quality Engineer Manager
Energy Product Development
Ethicon Endo-Surgery, Inc.

5/15/2015

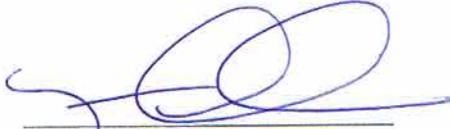
Date

Ethicon Endo-Surgery, LLC
510(k) Premarket Notification (Special)

HARMONIC FOCUS® Long Shears + Adaptive Tissue Technology

Declaration of Conformity: Manufacturing Facility

The manufacturing facility, Ethicon Endo-Surgery S.A. de C.V. Planta II, is in conformance with design control procedure requirements as specified in 21CFR 820.30 and the records are available for review.



Marjorie Medina
Senior Director, Quality Operations
Ethicon Endo-Surgery, LLC

05/15/2015
Date

15 May 2015
Confidential

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Section 12: Form FDA 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, LLC		2. Date of the Application/Submission Which This Certification Accompanies 05/15/2015	
3. Address		4. Telephone and Fax Numbers (Include country code if applicable and area code)	
Address 1 (Street address, P.O. box, company name c/o) 475 Calle L		(Tel): (787) 277-6654	
Address 2 (Apartment, suite, unit, building, floor, etc.)		(Fax): (787) 277-0042	
City Gauynabo	State/Province/Region PR		
Country USA	ZIP or Postal Code 00969		

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)

HARMONIC® Focus Long Shears + Adaptive Tissue Technology (HAR17F)

Continuation Page for #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)

If BLA was selected in item 6, provide Supplement Number

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 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 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 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.

Certification Statement / Information section continued on page 2

CERTIFICATION STATEMENT / INFORMATION (Continued)

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. (Add continuation page as necessary.)

NCT Number(s): _____

Continuation Page for #10

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. Name and Title of the Person who Signs Number 15

Name Brian Godwin	Title Senior Regulatory Affairs Associate
----------------------	--

12. Address

Address 1 (Street address, P.O. box, company name c/o) 4545 Creek Rd	
Address 2 (Apartment, suite, unit, building, floor, etc.)	
City Cincinnati	State/Province/Region OH
Country USA	ZIP or Postal Code 45242

13. Telephone and Fax Numbers

(Include country code if applicable and area code)

(Tel): (513) 337-3623

(Fax): (513) 337-4366

14. Date of Certification

15 MAY 15

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative (Sign)

Sign



This section applies only to requirements of the Paperwork Reduction Act of 1995.

*****DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*****

The burden time for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/ submission) per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 number."

Section 13: Form FDA 3654

This section contains completed copies of Form FDA 3654 for the standards referenced in this 510(k) submission. The referenced standards include the following:

IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-1-2:2007, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests (FDA Recognition Number 5-53)

ANSI/AAMI/ISO 11135:2007, Medical Devices - Validation & Routine Control of Ethylene Oxide Sterilization

ANSI/AAMI/ISO 11135:2014, Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices

ANSI/AAMI/ISO 10993-7:2008, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals (FDA Recognition Number 14-76)

AAMI/ANSI/ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process (FDA Recognition Number 2-156)

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 10993-7: 2008, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 14-278

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: Use of International Standard ISO-10993-7, "Biological Evaluation of Medical Devices Part 7:EO

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

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
AAMI ANSI ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

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 *
N/A, no deviations

DESCRIPTION
Scope of ISO-10993-8, EO Residuals

JUSTIFICATION
EO Sterilized Product - EO residual allowable levels

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 *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

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

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* 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.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
AAMI ANSI ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED *
Limited Exposure Devices - Simulated Use Extraction

DESCRIPTION
Limited exposure devices and simulated use extraction method used

JUSTIFICATION
Refer to IFU for the device intended use; simulated extraction method use - 24 hours extraction

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Product release	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Section 5.2 used - Release of products without dissipation curve data

DESCRIPTION
Simulated use extraction method to be used to qualify EO and ECH residuals after 24:00 hours heated aeration

JUSTIFICATION
Acceptable method for product release is based on Section 5.2 of the standard. Device to demonstrate EO and ECH levels below the specified limits in this guidance.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.3	Procedure for product release using residue dissipation curves	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Section of the Standard is being used for product release

DESCRIPTION
Acceptable method - Section 5.2 is being used for product release

JUSTIFICATION
Standard permits for either method for product release - Section 5.2 is being used for this product. Limited exposure device will demonstrate acceptable EO and ECH residual levels per ISO 10993-7.

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 14-331

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.

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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: Use of International Std ISO-11135-1:2007 - Sterilization of health care product - Ethylene Oxide Part 1

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

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development

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 [♦] Medical device terminally sterilized using EO.		
DESCRIPTION Defines scope of guidance document and exclusions		
JUSTIFICATION N/A		
2	Normative references	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED [♦] N/A		
DESCRIPTION Provides additional guidance references.		
JUSTIFICATION N/A		
3	Terms and definitions	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED [♦] N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Quality management systems	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION The contract sterilizer is certified to ISO 13485 and has procedures in place specifying requirements for documentation, management responsibility, purchasing of components, calibration and control of non-conforming product.		
JUSTIFICATION ISO Certificate		
5	Sterilizing agent characterization	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION Sterilizing agent characterization		
JUSTIFICATION EO and its anti-microbial effectiveness is well established and documented. Its use as a terminal sterilization method is common in the medical industry particularly with sensitive materials that are not gamma stable.		
6	Process and equipment characterization.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION Process and equipment characterization.		
JUSTIFICATION Steris-Isomedix is an established production sterilizer, and the facility and equipment have been fully validated on an annual basis by Depuy Synthes, a J&J Company. The cycle utilized is identical to the established Depuy Synthes production cycle.		

* 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.

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STANDARD TITLE
ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Product definition	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION Product Definition		
JUSTIFICATION Product performance and microbiological quality will be tested. Full sterilization validation activities for product adoption into the Depuy Synthes routine production cycle will be performed.		
8	Process definition	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION Process Definition		
JUSTIFICATION The production EO cycle to be used to terminally sterilize the device (achieving an SAL 10 ⁻⁶) is identical to the production cycle currently being used by Depuy Synthes devices, a J&J company.		
9	Validation	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION Validation		
JUSTIFICATION IQ/OQ activities were performed on the chamber/equipment. The procedures to qualify, sustain & control, calibrate, and re-validate the EO are documented in the Qual System. Micro. and performance qualification will demonstrate the EO sterilization acceptability.		
* 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.		
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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 11135-1: 2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10	Routine monitoring and control	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
Routine Monitoring and Control

JUSTIFICATION
Each production sterilization cycle will be monitored to ensure all parameters meet the required specifications.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
11	Product release from sterilization	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
Product Release from Sterilization

JUSTIFICATION
Each production sterilization cycle will be monitored to ensure all parameters meet the required specifications. Non-conformances will be handled through the Quality System.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
12	Maintaining process effectiveness	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
Maintaining Process Effectiveness

JUSTIFICATION
Bioburden will be routinely monitored on a quarterly basis. All routine maintenance and calibration of EO sterilizing equipment will be performed and documented. Annual re-qualification will be completed. Changes to the device will be evaluated.

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

AAMI ANSI ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk mngmnt process

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #2-156

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)?
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Does this standard include acceptance criteria?
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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 Bluebook Memorandum G95-1, Use of International Standard ISO 10993, "Biological Evaluation of

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

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
AAMI ANSI ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk mngmnt process

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope, object and related standards	<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	Terminology and definitions	<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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STANDARD TITLE
AAMI ANSI ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk mngmnt process

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	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

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Categorization 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

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Biological evaluation process	<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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CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Interpretation of biological evaluation data and overall biological safety asses	<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 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 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.

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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

IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? Yes No

FDA Recognition number ³ # N/A

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? Yes No

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? Yes No
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? Yes No

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

Does this standard include more than one option or selection of tests? Yes No
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?..... Yes No
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? Yes No

Were deviations or adaptations made beyond what is specified in the FDA SIS?..... Yes No
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? Yes No
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?..... Yes No
If yes, was the guidance document followed in preparation of this 510k? Yes No

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], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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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>

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope, object, and related standards	<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	Terminology and definitions	<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
IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	General requirements	<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?
5	General requirements for testing ME equipment	<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?
6	Classification of ME equipment and ME systems	<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
IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 7	SECTION TITLE ME equipment identifications, marking and documents	CONFORMANCE? <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 8	SECTION TITLE Protection against electrical hazards from ME equipment	CONFORMANCE? <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 9	SECTION TITLE Protection against mechanical hazards and ME equipment and ME systems	CONFORMANCE? <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

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10	Protection against unwanted and excessive radiation hazards	<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?
11	Protection against excessive temperatures and other hazards	<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?
12	Accuracy of controls and instruments and protection against hazardous output	<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
IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 13	SECTION TITLE Hazardous situations and fault conditions	CONFORMANCE? <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 14	SECTION TITLE Programmable electrical medical systems (PEMS)	CONFORMANCE? <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 15	SECTION TITLE Construction of ME equipment	CONFORMANCE? <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

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STANDARD TITLE
IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
16	ME systems	<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?
17	Electromagnetic compatibility of ME equipment and ME systems	<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 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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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #5-53

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], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope, object, and related standards	<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	Terminology and definitions	<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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SUMMARY REPORT TABLE**

STANDARD TITLE
IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	General requirements	<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?
5	Identification, marking, and documents	<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?
6	Electromagnetic compatibility	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ANSI/AAMI/ISO 11135:2014, Medical Devices - Validation & Routine Control of Ethylene Oxide Sterilization

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 14-452

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)?
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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: Use of International Std ISO-11135-1:2014 - Sterilization of health care product - Ethylene Oxide

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

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ANSI/AAMI/ISO 11135:2014, Medical Devices - Validation & Routine Control of Ethylene Oxide Sterilization

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
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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
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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
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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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"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."

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ANSI/AAMI/ISO 11135:2014, Medical Devices - Validation & Routine Control of Ethylene Oxide Sterilization

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 4	SECTION TITLE Quality management 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 5	SECTION TITLE Sterilizing agent characterization	CONFORMANCE? <input 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 *		
DESCRIPTION		
JUSTIFICATION		
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 *		
DESCRIPTION		
JUSTIFICATION		

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ANSI/AAMI/ISO 11135:2014, Medical Devices - Validation & Routine Control of Ethylene Oxide Sterilization

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 8	SECTION TITLE Process definition	CONFORMANCE? <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 9	SECTION TITLE Validation	CONFORMANCE? <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 10	SECTION TITLE Routine control and monitoring	CONFORMANCE? <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 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

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ANSI/AAMI/ISO 11135:2014, Medical Devices - Validation & Routine Control of Ethylene Oxide Sterilization

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 12	SECTION TITLE Maintaining process effectiveness	CONFORMANCE? <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? <input 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? <input 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? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED [♦]

DESCRIPTION

JUSTIFICATION

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K151340/S001

ETHICON

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23 June 2015

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

FDA CDRH DMC

JUN 24 2015

Received

Re: **K151340** , **Deficiency Responses**

Dear Mr. Long Chen

Attached please find the responses to the Deficiency Letter for K151340 dated 08 June 2015.

Per the FDA Guidance for Industry “*eCopy Program for Medical Device Submissions*,” the eCopy is an exact duplicate of the paper copy enclosed.

If there are any questions concerning this notification, please contact me at (513) 337-3623 or by email at bgodwin@its.jnj.com. If I am not available, the alternate contact person for this submission is Hortense Allison, Director, Regulatory Affairs, at (513) 337-3592.

Sincerely,



Brian Godwin, RAC
Senior Regulatory Affairs Associate

Enclosure



23 June 2015

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

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Sincerely,

A handwritten signature in black ink, appearing to read "Brian Godwin".

Brian Godwin, RAC
Senior Regulatory Affairs Associate

Enclosure

FDA Question

(b)(4)

A large black rectangular redaction box covering the entire content of the first FDA Question section.

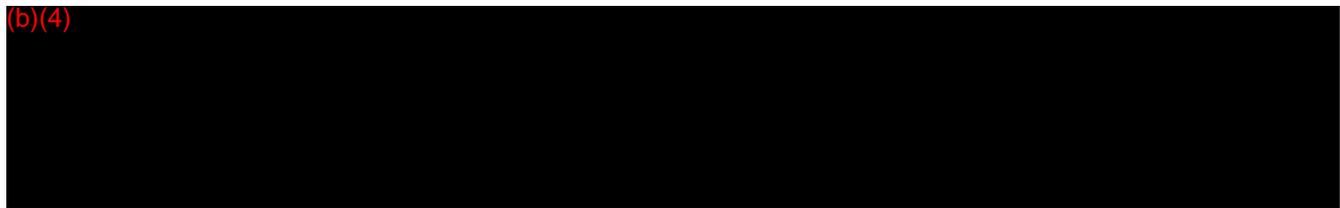
Response

(b)(4)

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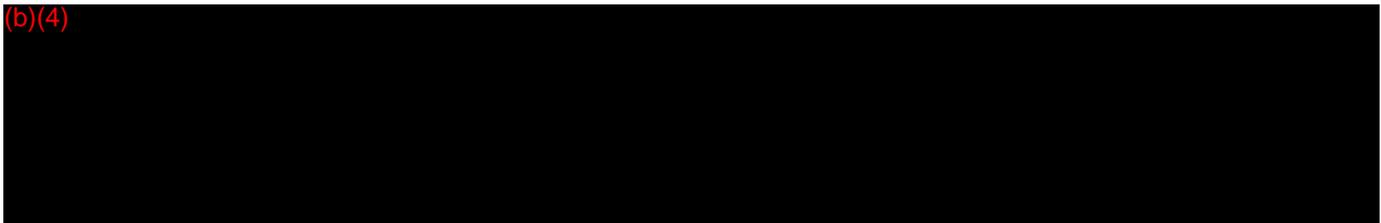
FDA Question

(b)(4)

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Response

(b)(4)

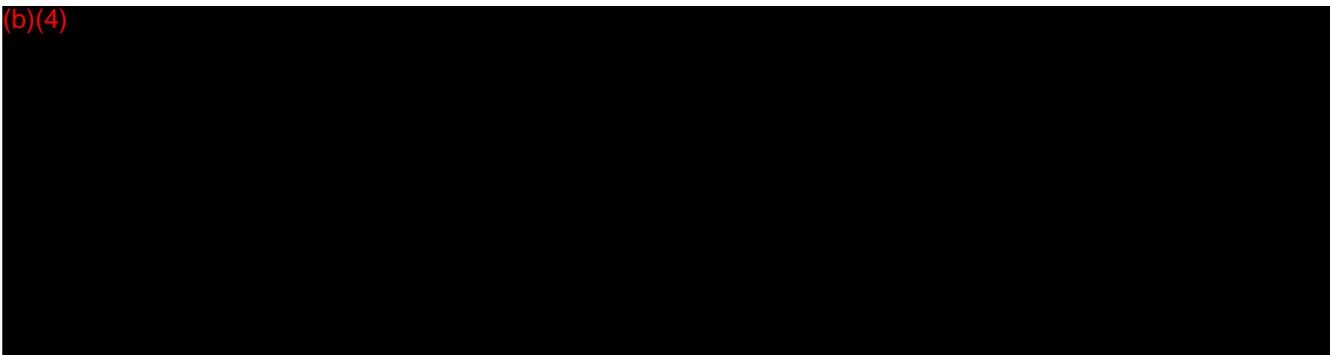
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FDA Question

(b)(4)

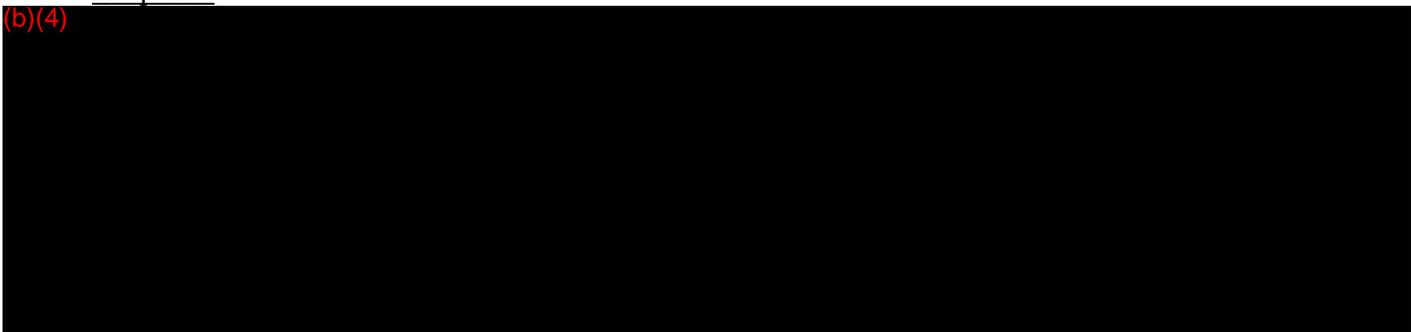
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(b)(4)



Response

(b)(4)



Attachment 1

Complaint Analysis for Harmonic Focus Shears (FCS9) and Harmonic Focus Shears + Adaptive Tissue Technology (HAR9F)



EPICenter



Document Number: (b)(4)
Revision: (b)(4)
Group: Scanned (Hardcopy) Item
Type: DBAM
State: Released
Latest Released: YES
Implemented Date: 01/22/2015
Stamp Date: Thursday, 22 January, 2015 10:08:03 AM EST

SCN005376 Revision



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M E M O R A N D U M

Date: June 22, 2007
Revision: January 9, 2008
Revision: June 29, 2009
Revision: (b)(4)
Revision: [Redacted]
Revision: [Redacted]

From: (b)(6)
Principal Scientist – Biocompatibility Toxicologist

To: Brian Godwin

Subject: Device Biocompatibility Approval for Harmonic Focus, and Blue Torque Wrench (SCN005376)

(b)(4)
[Large redacted block]

Device Information:

Product Code	Product Name
FCS9	Harmonic Focus

Rev E

(b)(4)
[Redacted block]

(b)(4)

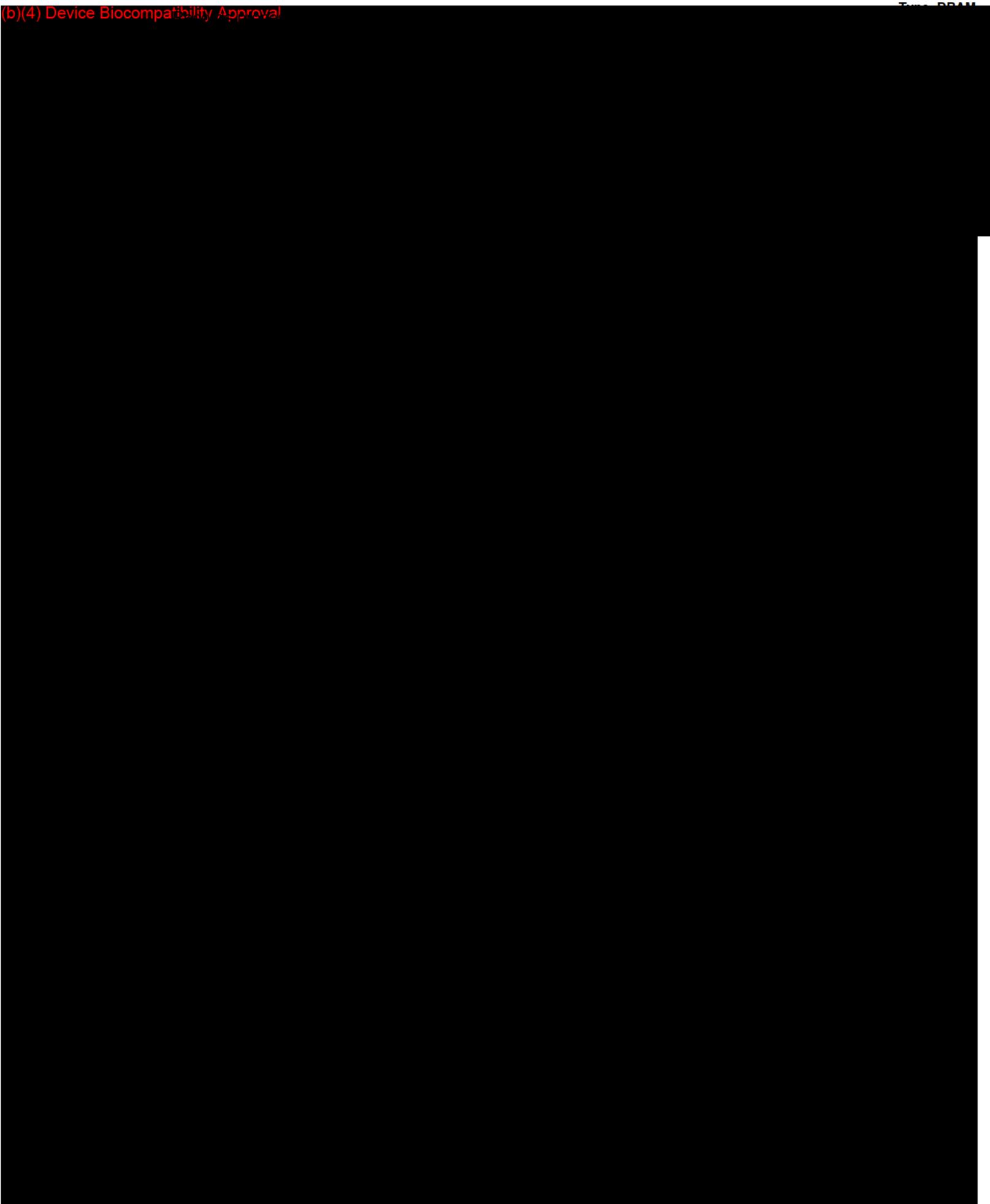
Type: DBAM

(b)(4) Device Biocompatibility Approval

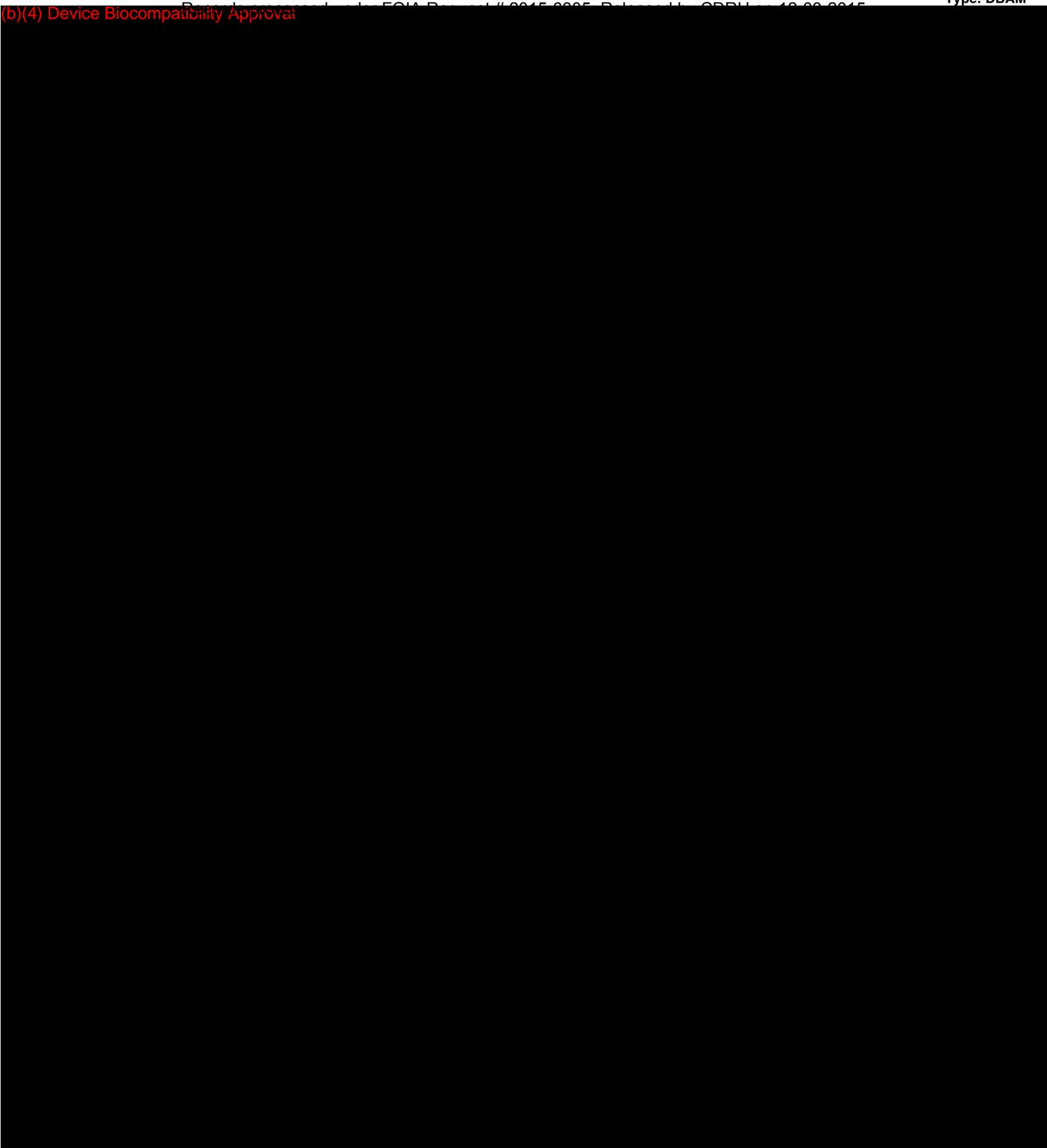
FOIA Request # 2015-6205; Released by CDRH on 12-02-2015

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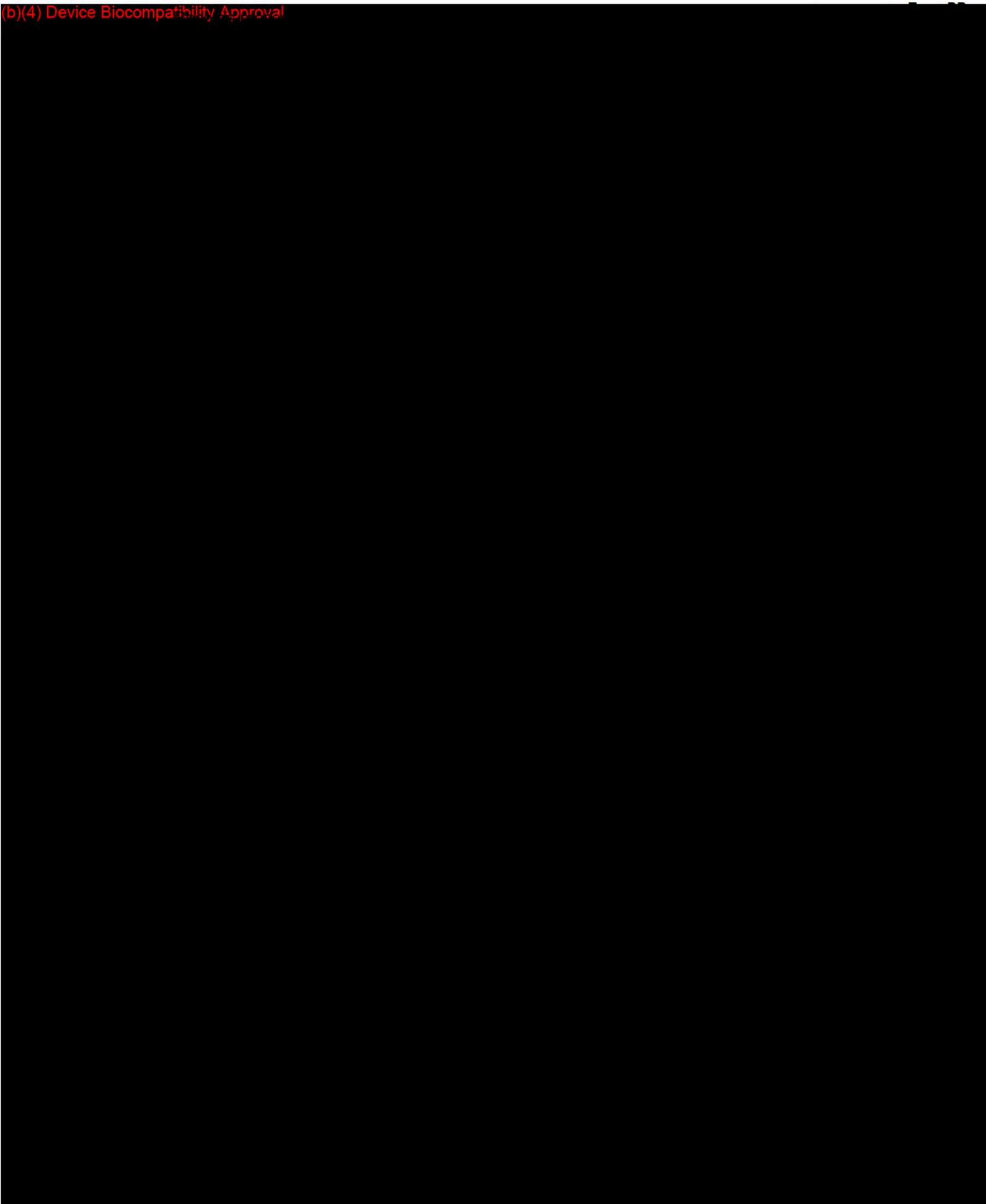
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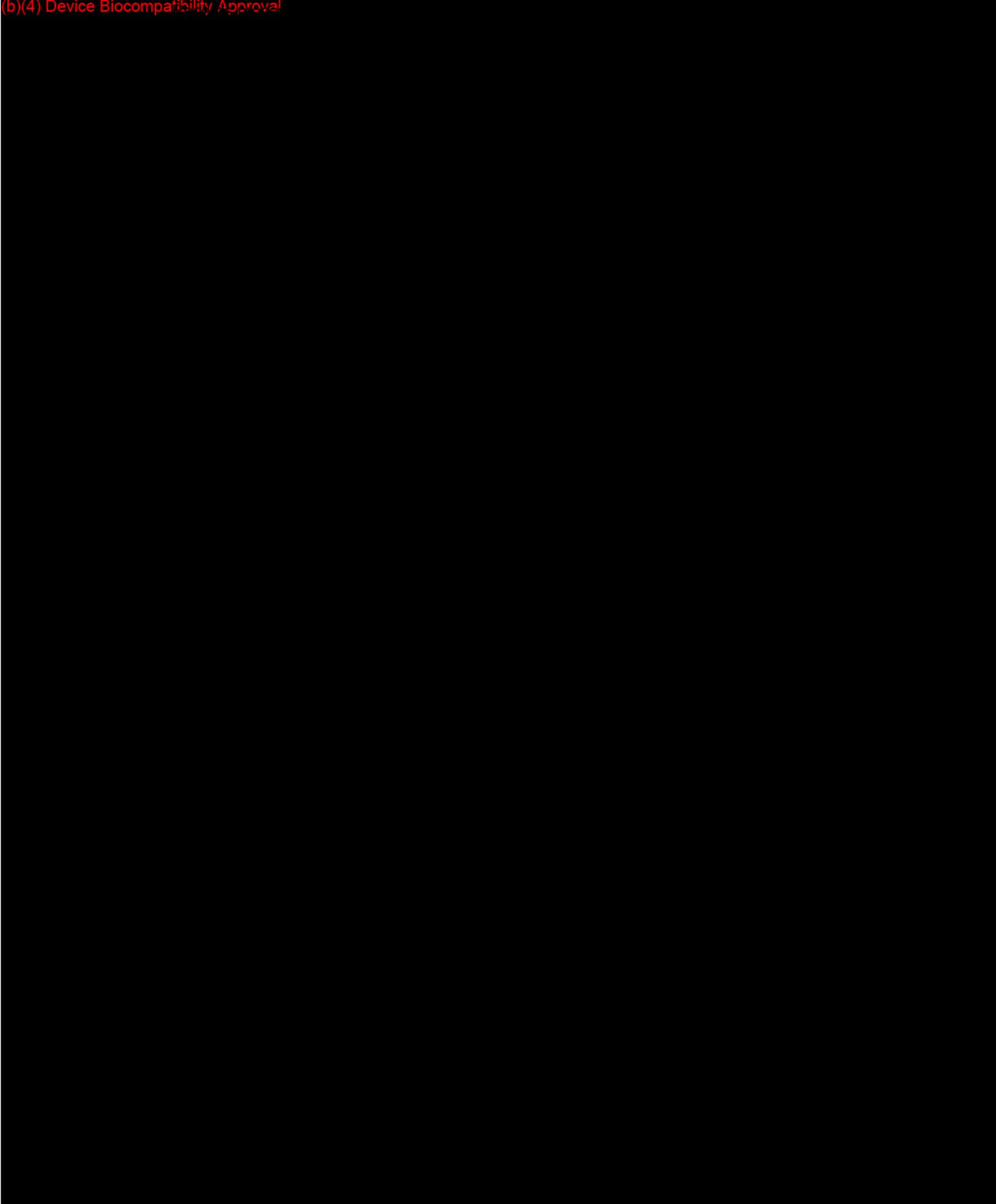
(b)(4) Device Biocompatibility Approval



(b)(4) Device Biocompatibility Approval

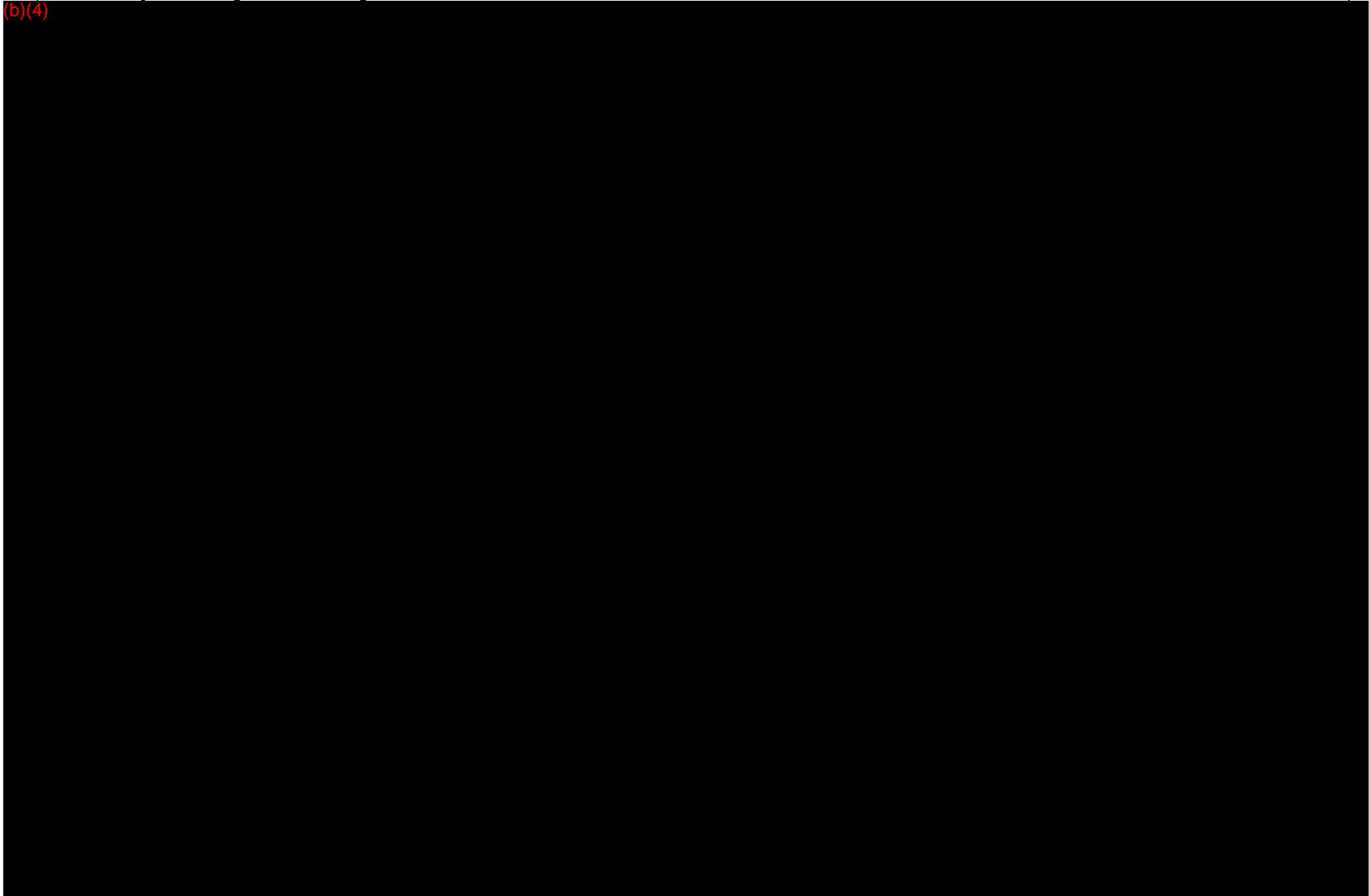


(b)(4) Device Biocompatibility Approval



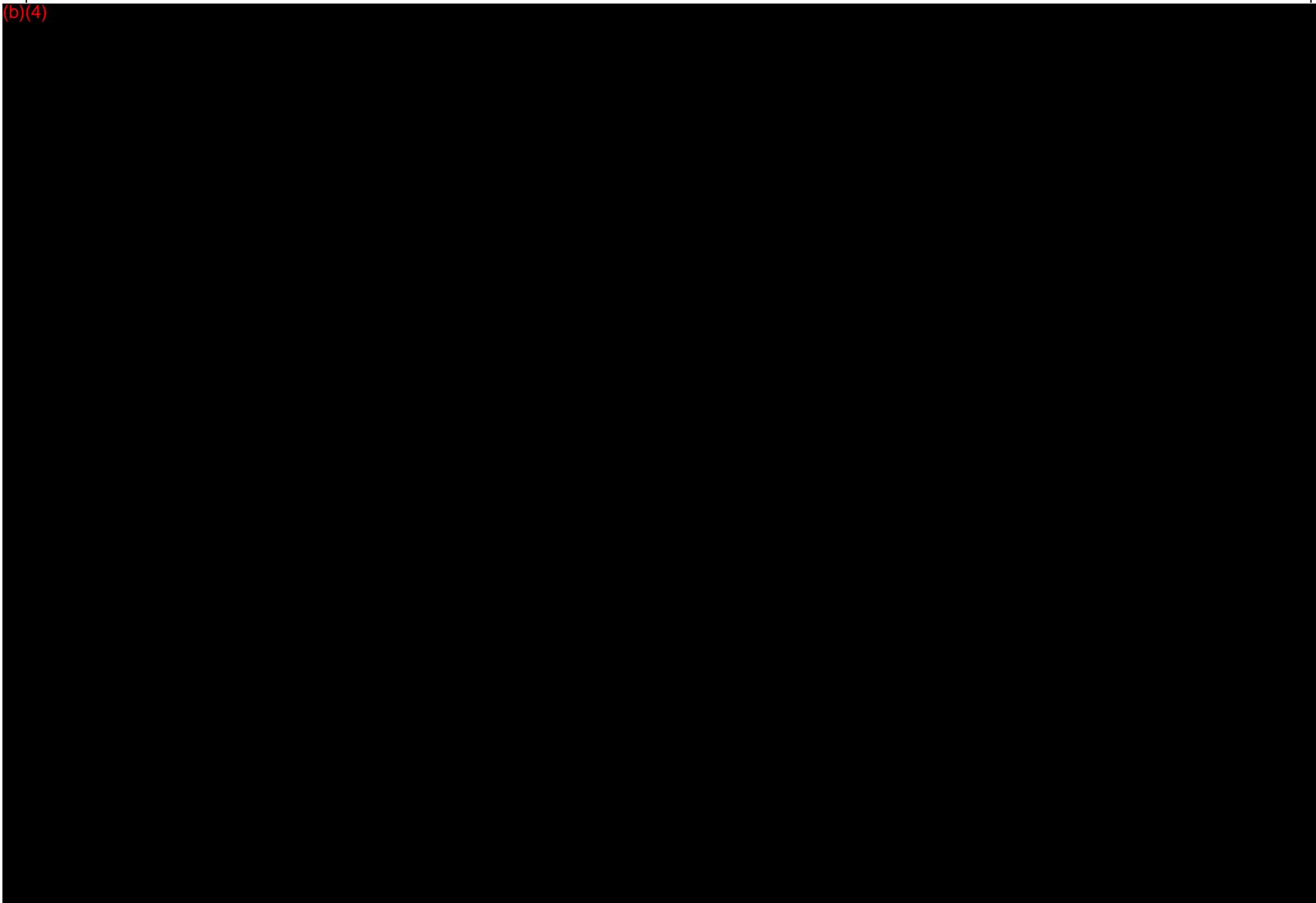
(b)(4) Biocompatibility

Biocompatibility Summary for Focus FCS9



(b)(4)

(b)(4)



(b)(4)

Biocompatibility Summary for Focus FCS9

Part Name/Number	Material Generic Name / Color	Material Trade Name	Material Supplier	Material Additives	Material Rspec	Contact Category Required	Testing
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(b)(4)

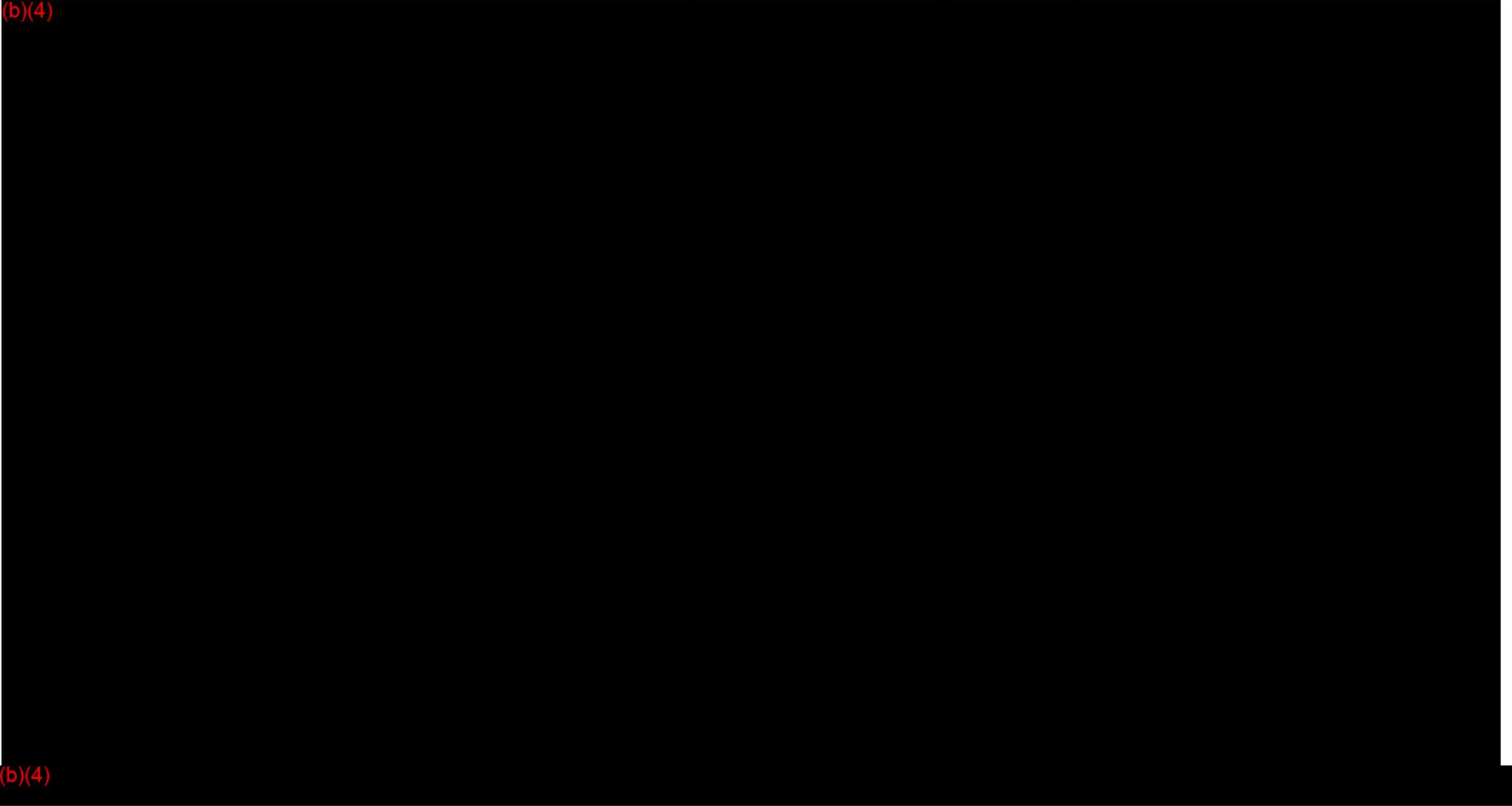


(b)(4)

Biocompatibility Summary for Focus FCS9

	Material Generic Name	Material Trade	Material	Material	Material	Contact Category	
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(b)(4)

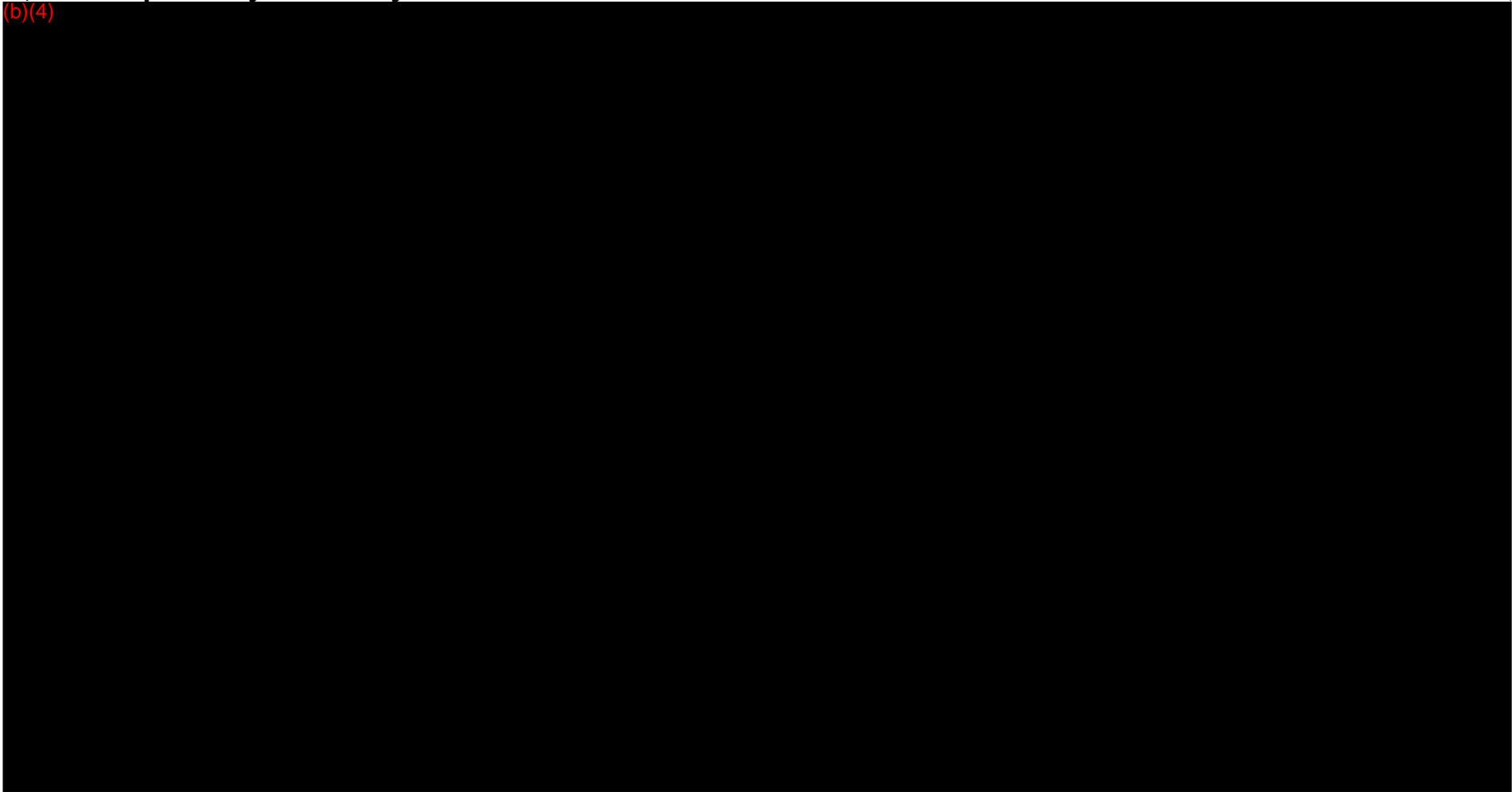


(b)(4)

(b)(4)

Biocompatibility Summary for Focus FCS9

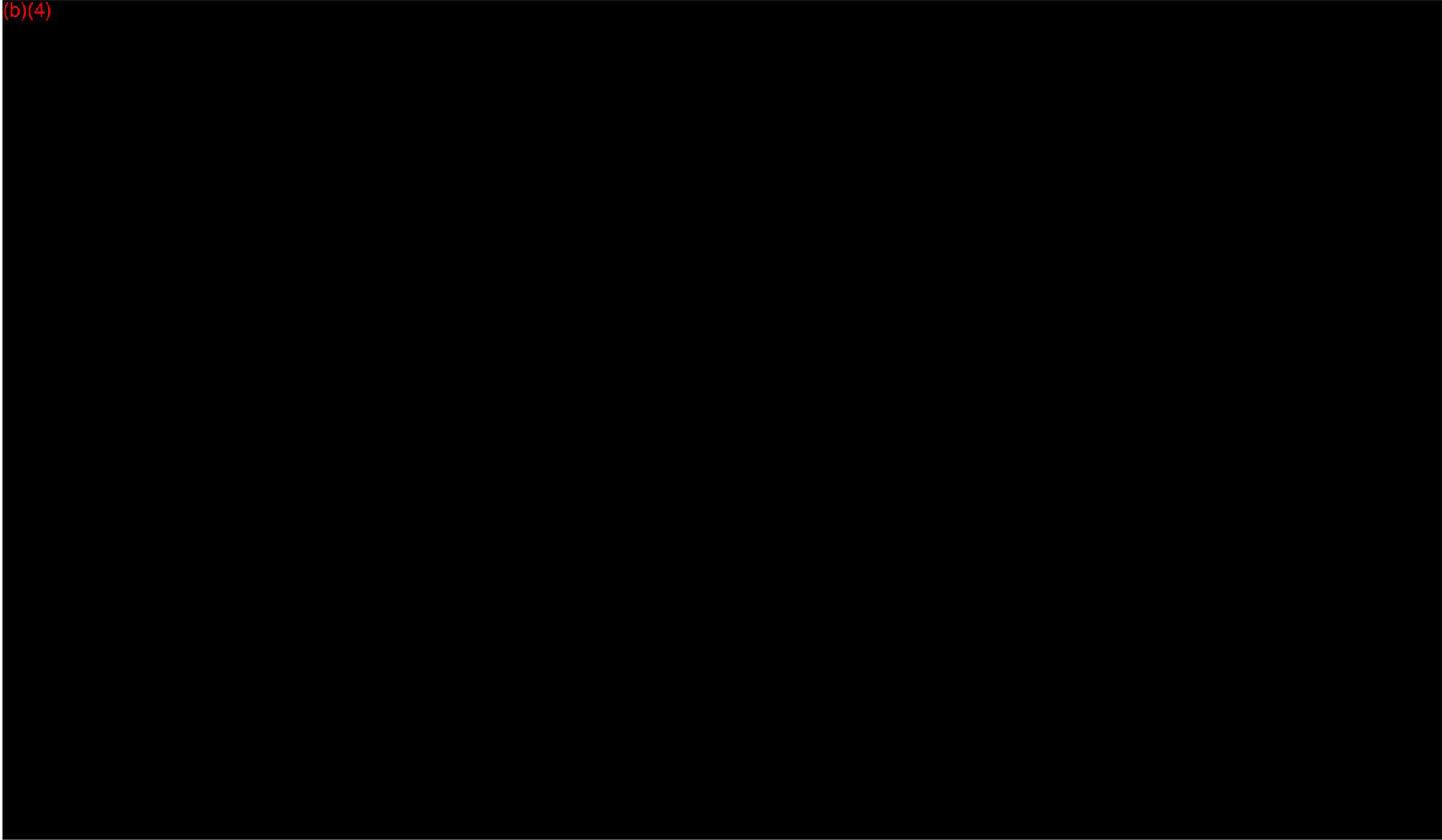
(b)(4)



(b)(4)

Biocompatibility Summary for Focus FCS9

(b)(4)



(b)(4)

Biocompatibility Summary for Focus FCS9

(b)(4)



Attachment 4

Design Verification Summary for HAR17F

