

**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

DEC 03 2013

**Date Prepared** 20 November 2013

**Device Name**

Trade Name: HARMONIC FOCUS Shears + Adaptive Tissue Technology  
Common Name: Instrument, Ultrasonic Surgical

**Classification Name**

Instrument, Ultrasonic Surgical (Unassigned, Product Code LFL)

**Predicate Device**

HARMONIC FOCUS® Shears, cleared under K100597 on 07 April 2010

**Device Description**

The Ethicon Endo-Surgery HARMONIC FOCUS Shears + Adaptive Tissue Technology is a sterile, single-patient use surgical 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's working length is 9 cm in length with a 16 mm active blade length. The instrument allows for the cutting and coagulation of vessels up to and including 5 mm in diameter.

**Indications for Use**

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.

### **Technological Characteristics**

The HARMONIC FOCUS Shears + Adaptive Tissue Technology use an EEPROM memory chip that stores device identification, usage tracking, and operating parameters for use by the Generator G11 that provides power for the HARMONIC FOCUS Shears + Adaptive Tissue Technology. Adaptive Tissue Technology refers to the power output algorithm that is utilized by the devices. During use, the Adaptive Tissue Technology algorithm parameters stored on the device EEPROM are read by the generator and used to reduce the power (current) to the instrument and provide a secondary, higher pitched generator activation tone as Adaptive Tissue Technology regulates the delivery of energy. To do this the generator monitors the thermal condition of the blade during device activation.

### **Performance Data**

#### *Non-clinical and Preclinical Performance Testing*

Biocompatibility studies, electrical safety testing, and EMC testing were performed. The results demonstrate the HARMONIC FOCUS Shears + Adaptive Tissue Technology device performance was equivalent to the predicate. In addition, preclinical laboratory evaluations in an animal model were performed, which included acute and 30-day chronic survival studies. The results of those evaluations demonstrate that the HARMONIC FOCUS Shears + Adaptive Tissue Technology effectively cut and coagulated vessels 1 to 5mm in diameter.

#### *Clinical Performance*

This premarket notification does not rely on data from human clinical trials to demonstrate substantial equivalence. Clearance was based on non-clinical and preclinical testing.

### **Conclusion**

The results of the bench testing and laboratory evaluations in an animal model demonstrate that the HARMONIC FOCUS 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.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-0609  
Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, Inc.  
Mr. Brian Godwin, RAC  
Senior Regulatory Affairs Associate  
4545 Creek Road  
Cincinnati, Ohio 45242

December 3, 2013

Re: K133314

Trade/Device Name: HARMONIC FOCUS<sup>®</sup> Shears + Adaptive Tissue Technology

Regulatory Class: Unclassified

Product Code: LFL

Dated: October 25, 2013

Received: October 29, 2013

Dear Mr. Godwin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Brian Godwin

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Joshua C. Nipper -S**

**FOR** Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K133314

**Device Name:**

HARMONIC FOCUS® Shears + Adaptive Tissue Technology

**Indications for Use:**

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.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen - A

Digitally signed by Long H. Chen - A  
DN: cn=US, o=U.S. Government, ou=FDA,  
ou=FDA, ou=People, cn=Long H. Chen - A,  
c=US, email=long.h.chen@FDA.gov

for BSA

(Division Sign-off)

Division of Surgical Devices

510(k) Number K133314



29 October 2013

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: **K133314 User Fee Hold Letter:**  
**Ethicon Endo-Surgery HARMONIC FOCUS® Shears + Adaptive Tissue Technology**

Dear Sir or Madam:

This correspondence is in response to the User Fee Hold Letter dated 28 October 2013 for K133314, which indicates that the User Fee for the 510(k) was not received.

Included in this correspondence (4 pages total, including this cover letter) are the following documents which verify that the User Fee payment associated with this traditional 510(k) was provided in full:

- the completed FDA Form 3601 that was submitted in the 510(k) submission
- a photocopy of the check that was sent to address located on the check
- the FedEx receipt confirming delivery of the check covering the User Fee (\$5,170) for the 510(k) submission.

If there are any questions concerning this notification, please contact me at (513) 337-3623 or by email at [bgodwin@its.jnj.com](mailto:bgodwin@its.jnj.com). If I am not available, the alternate contact person for this submission (b)(6) (b)(6) (b)(6)

Sincerely,

Brian Godwin, RAC  
Senior Regulatory Affairs Associate  
Ethicon Endo-Surgery, Inc.  
4545 Creek Road, ML 39  
Cincinnati, OH 45242

*Enclosure*

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: <a href="http://www.fda.gov/oc/mdufma/cover-sheet.html">http://www.fda.gov/oc/mdufma/cover-sheet.html</a>		
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 Brian Godwin 2.1 E-MAIL ADDRESS bgodwin@ils.jnj.com 2.2 TELEPHONE NUMBER (include Area code) 513-337-3023 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 513-337-4368	
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: <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm</a> ) Select an application type: <input checked="" type="checkbox"/> Premarket notification (510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice		
3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)		
4. ARE YOU A SMALL BUSINESS? (See the Instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm</a> 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"/> The sole purpose of the application is to support conditions of use for a pediatric population <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 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, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 (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)		

17-Sep-2013

Form FDA 3601 (01/2007)

ETHICON ENDO-SURGERY, INC  
P.O. BOX 16500-6500  
NEW BRUNSWICK, NJ 08906

*Johnson & Johnson*  
SERVICES, INC.  
As Paying Agent

RETURN SERVICE REQUESTED

Check No.  
Check Date  
Check Amount  
Vendor No.

(b)(4)



(b)(4)  
FOOD AND DRUG ADMINISTRATION  
GOVT LOCKBOX 956733  
1005 CONVENTION PLAZA  
SAINT LOUIS, MO 63101-0000

Invoice Date	Invoice Number	Description	Gross Amount	Discount Amount	Net Amount
09/23/2013	(b)(4)	FDA USER FEE_ (b)(4)			(b)(4)
TOTAL					(b)(4)

PLEASE FOLD ON PERFORATION AND DETACH HERE

VERIFY THE AUTHENTICITY OF THIS MULTI-TONE SECURITY DOCUMENT. CHECK BACKGROUND AREA CHANGES COLOR GRADUALLY FROM TOP TO BOTTOM.

ETHICON ENDO-SURGERY, INC  
P.O. BOX 16500-6500  
NEW BRUNSWICK, NJ 08906

*Johnson & Johnson*  
SERVICES, INC.  
As Paying Agent

(b)(4)  
September 21, 2013  
VOID AFTER 180 DAYS

Amount: (b)(4)  
Pay to the order of  
FOOD AND DRUG ADMINISTRATION  
GOVT LOCKBOX 956733  
1005 CONVENTION PLAZA  
SAINT LOUIS, MO 63101-0000

(b)(4)

Bank of America N.A.  
Atlanta, DeKalb County, GA

*[Signature]*  
AUTHORIZED SIGNATURE



**796797638100**

<p>SNP (PAU) date:  <b>Mon 9/30/2013 3:57 pm</b>          Ethicon Endo Surgery          Jonis McGee          4645 Creek Rd., ML 132          Cincinnati, OH US 45242          513 337-7568</p>	 <b>Delivered</b> <i>Signed for by: MEREL</i>	<p>Actual delivery:  <b>Tues 10/01/2013 9:38 am</b>          Food &amp; Drug Administration/US          Bank          Attn: Government Lockbox 056733          1005 CONVENTION PLZ          SAINT LOUIS, MO US 63101          301 798-7200</p>
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**Travel History**

Date/Time	Activity	Location
- 10/01/2013 - Tuesday		
9:38 am	Delivered	SAINT LOUIS, MO
8:06 am	On FedEx vehicle for delivery	ST. LOUIS, MO
7:01 am	At local FedEx facility	ST. LOUIS, MO
6:22 am	At destination sort facility	BERKLEY, MO
4:34 am	Departed FedEx location	MEMPHIS, TN
- 9/30/2013 - Monday		
11:18 pm	Arrived at FedEx location	MEMPHIS, TN
9:18 pm	Left FedEx origin facility	LOVELAND, OH
3:57 pm	Picked up	LOVELAND, OH
10:05 am	Shipment information sent to FedEx	

Local Scan Time: [ ]

**Shipment Facts**

Tracking number	796797638100	Service	FedEx Standard Overnight
Weight	0.5 lbs	Delivery attempts	1
Delivered To	Mailroom	Total pieces	1
Total shipment weight	0.5 lbs / 0.2 kgs	Terms	Not Available
Purchase order number	Godwin-Nighthawk	Department number	2010002565
Shipper reference	2010002564	Packaging	FedEx Envelope
Special handling section	Deliver Weekday		

K133314

Form Approved OMB No. 0911-0511 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) (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: <a href="http://www.fda.gov/oc/mdufma/cover-sheet.html">http://www.fda.gov/oc/mdufma/cover-sheet.html</a>			
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Form FDA 2609 (01/2007)



ETHICON ENDO-SURGERY, INC  
 P.O. BOX 16500-6500  
 NEW BRUNSWICK, NJ 08906

*Johnson & Johnson*  
 SERVICES, INC.  
 As Paying Agent

RETURN SERVICE REQUESTED

Check No. (b)(4)  
 Check Date  
 Check Amount  
 Vendor No.



0D-300111 0001 0001 000111  
 FOOD AND DRUG ADMINISTRATION  
 GOVT LOCKBOX 956733  
 1005 CONVENTION PLAZA  
 SAINT LOUIS, MO 63101-0000

Invoice Date	Invoice Number	Description	Gross Amount	Discount Amount	Net Amount
09/23/2013	(b)(4)	FDA USER FEE (b)(4)			(b)(4)
TOTAL					(b)(4)

PLEASE FOLD ON PERFORATION AND DETACH HERE

VERIFY THE AUTHENTICITY OF THIS MULTI-TONE SECURITY DOCUMENT.

CHECK BACKGROUND AREA CHANGES COLOR GRADUALLY FROM TOP TO BOTTOM.

ETHICON ENDO-SURGERY, INC  
 P.O. BOX 16500-6500  
 NEW BRUNSWICK, NJ 08906

*Johnson & Johnson*  
 SERVICES, INC.  
 As Paying Agent

(b)(4)  
 September 24, 2013  
 64-1278/611  
 VOID AFTER 180 DAYS

Amount: (b)(4)

(b)(4)

Pay to the order of  
 FOOD AND DRUG ADMINISTRATION  
 GOVT LOCKBOX 956733  
 1005 CONVENTION PLAZA  
 SAINT LOUIS, MO 63101-0000

Bank of America N.A.  
 Atlanta, DeKalb County, GA

*[Signature]*  
 AUTHORIZED SIGNATURE

(b)(4)



**796797638100**

Ship (PU) date :  
**Mon 9/30/2013 3:57 pm**  
 Ethicon Endo Surgery  
 Jonie McGee  
 4545 Creek Rd , Mt 132  
 Cincinnati, OH US 45242  
 513 337-7568



**Delivered**  
 Signed for by: *ET EBET*

Actual delivery :  
**Tues 10/01/2013 9:38 am**  
 Food & Drug Administration-US  
 Bank  
 Attn: Government Lockbox 956733  
 1005 CONVENTION PLZ  
 SAINT LOUIS, MO US 63101  
 301 796-7200

**Travel History**

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7:01 am	At local FedEx facility	ST. LOUIS, MO
5:22 am	At destination sort facility	MEMPHIS, TN
4:34 am	Departed FedEx location	MEMPHIS, TN
- 9/30/2013 - Monday		
11:16 pm	Arrived at FedEx location	MEMPHIS, TN
9:18 pm	Left FedEx origin facility	LOVELAND, OH
3:57 pm	Picked up	LOVELAND, OH
10:05 am	Shipment information sent to FedEx	

Local Scan Time

**Shipment Facts**

Tracking number	796797638100	Service	FedEx Standard Overnight
Weight	0.5 lbs	Delivery attempts	1
Delivered To	Mailroom	Total pieces	1
Total shipment weight	0.5 lbs / 0.2 kgs	Terms	Not Available
Purchase order number	Godwin-Highthawk	Department number	2010002555
Shipper reference	2010002564	Packaging	FedEx Envelope
Special handling section	Deliver Weekly		



29 October 2013

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: **K133314 User Fee Hold Letter:**

**Ethicon Endo-Surgery HARMONIC FOCUS® Shears + Adaptive Tissue Technology**

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(b) (6) (b)(4)

Sincerely,

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

Brian Godwin, RAC  
Senior Regulatory Affairs Associate  
Ethicon Endo-Surgery, Inc.  
4545 Creek Road, ML 39  
Cincinnati, OH 45242

*Enclosure*



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G1609  
Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, Inc.  
Mr. Brian Godwin, RAC  
Senior Regulatory Affairs Associate  
4545 Creek Road  
Cincinnati, Ohio 45242

December 3, 2013

Re: K133314

Trade/Device Name: HARMONIC FOCUS<sup>®</sup> Shears + Adaptive Tissue Technology  
Regulatory Class: Unclassified  
Product Code: LFL  
Dated: October 25, 2013  
Received: October 29, 2013

Dear Mr. Godwin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Brian Godwin

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Joshua C. Nipper -S**

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Page 3 – Mr. Brian Godwin

**Concurrence & Template History Page**

[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number:K133314

For Office of Compliance Contact Information:

[http://insideportlets.fda.gov:9010/portal/page?\\_pageid=197.415881&\\_dad=portal&\\_schema=PORTAL&org=318](http://insideportlets.fda.gov:9010/portal/page?_pageid=197.415881&_dad=portal&_schema=PORTAL&org=318)

For Office of Surveillance and Biometrics Contact Information:

[http://insideportlets.fda.gov:9010/portal/page?\\_pageid=197.415881&\\_dad=portal&\\_schema=PORTAL&org=423](http://insideportlets.fda.gov:9010/portal/page?_pageid=197.415881&_dad=portal&_schema=PORTAL&org=423)

<b>Digital Signature Concurrence Table</b>	
Reviewer Sign-Off	Jennifer Stevenson 11-22-13
Branch Chief Sign-Off	Long Chen 11/22/2013
Division Sign-Off	Digitally signed by Joshua C. Nipper -S Date: 2013.12.03 12:21:12 -05'00'

f/t:JRS:d1m:11/22/13

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1 <sup>st</sup> page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".
4/2/2013	M. McCabe Janicki	Edited sentence that starts "If you desire specific advice for your device on our labeling regulation (21 CFR Part 801)..." Replaced broken Compliance link with general link to DSMICA.
4/12/2013	Margaret McCabe Janicki	Fixed a typo: Paragraph 1, final sentence, "We remind you, however; that device labeling must be truthful..." Replaced incorrect semicolon with a comma.

**Indications for Use**

510(k) Number (if known): K133314

**Device Name:**

HARMONIC FOCUS<sup>®</sup> Shears + Adaptive Tissue Technology

**Indications for Use:**

The HARMONIC FOCUS<sup>®</sup> 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.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A

Digitally signed by Long H. Chen -A  
DN: cn=US, o=U.S. Government, ou=HHS,  
ou=FDA, ou=People, cn=Long H. Chen -A,  
c=US, email=long.h.chen@fda.hhs.gov,  
date=2015.11.27 13:46:15 -0500

for BSA

(Division Sign-off)

Division of Surgical Devices

510(k) Number K133314

K133314



FDA CDRH DMC  
OCT 28 2013  
Received

25 October 2013

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

Re: **Traditional 510(k) Premarket Notification:**

**Ethicon Endo-Surgery HARMONIC FOCUS® Shears + Adaptive Tissue Technology**

Dear Sir or Madam:

Pursuant to 21 CFR 807.90, Ethicon Endo-Surgery is submitting two copies of this traditional 510(k) premarket notification for the Ethicon Endo-Surgery Harmonic Focus Shears + Adaptive Tissue Technology. The design of the new device is based upon the predicate device Harmonic Focus Shears, cleared under K100597 on 07 April 2010.

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

Submission Type: Traditional 510(k)  
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](mailto: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: K100597

Handwritten initials/signature

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

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

Payment of the user fee has been made. A unique payment identification number (PIN) has been assigned to this submission, it is (b)(4). 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. The electronic copy is accompanied by extra copies of the 510(k) cover letter and the 510(k) truthful and accuracy statement with original signatures.

If there are any questions concerning this notification, please contact me at (513) 337-3623 or by email at [bgodwin@its.ini.com](mailto:bgodwin@its.ini.com). If I am not available, the alternate contact person for this submission is (b)(6).

(b)(6) (b)(4)

Sincerely,

Brian Godwin, RAC  
Senior Regulatory Affairs Associate

Enclosure

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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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>		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: <a href="http://www.fda.gov/oc/mdufma/cover sheet.html">http://www.fda.gov/oc/mdufma/cover sheet.html</a>		
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 Brian Godwin  2.1 E-MAIL ADDRESS bgodwin@its.jnj.com  2.2 TELEPHONE NUMBER (include Area code) 513-337-3623  2.3 FACSIMILE (FAX) NUMBER (Include Area code) 513-337-4366	
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: <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm</a> ) Select an application type:		
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER  3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm</a> 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, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [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)		17-Sep-2013

**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 10/25/2013	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)
----------------------------------	--------------------------------------	---

SECTION A TYPE OF SUBMISSION				
<b>PMA</b> <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	<b>PMA &amp; HDE Supplement</b> <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	<b>PDP</b> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<b>510(k)</b> <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<b>Request for Feedback</b> <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):
<b>IDE</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption (HDE)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<b>Class II Exemption Petition</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation (De Novo)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submission</b> <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) (b)(4)	
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 Director, Plant Quality		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) 337-3623	
Street Address 4545 Creek Road		FAX Number (including area code) (513) 337-4366	
City Cincinnati	State / Province Ohio	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** Records processed under **REASON FOR APPLICATION - PMA, PDP, OR IDE** DRH on 02-01-2016

<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** Records processed **ADDITIONAL INFORMATION ON 510(k) SUBMISSIONS** CDRH on 02-01-2016

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	K100597	HARMONIC FOCUS® Shears	Ethicon Endo-Surgery, LLC
2			
3			
4			
5			
6			

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

Common or usual name or classification name  
Instrument, Ultrasonic Surgical

	Trade or Proprietary or Model Name for This Device	Model Number
1	HARMONIC FOCUS® Shears + Adaptive Tissue Technology	1 HAR9F
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 & Plastic Surgery		

Indications (from labeling)

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.

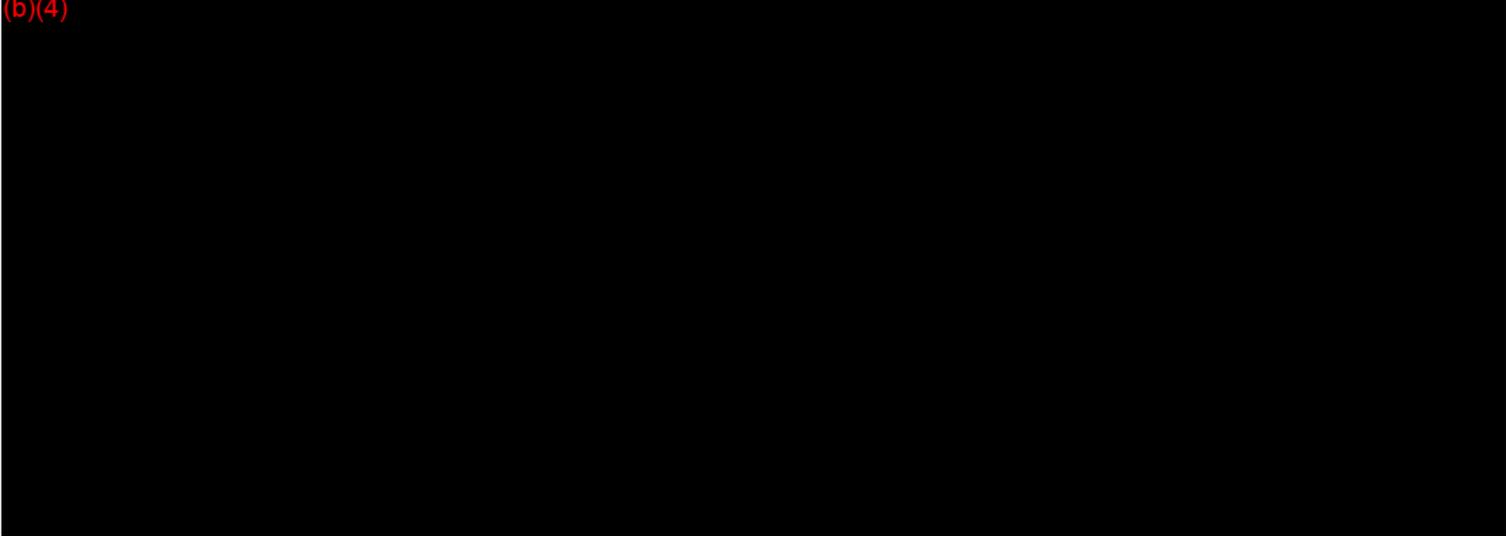
**Note:** Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDAB Form Number (if known)

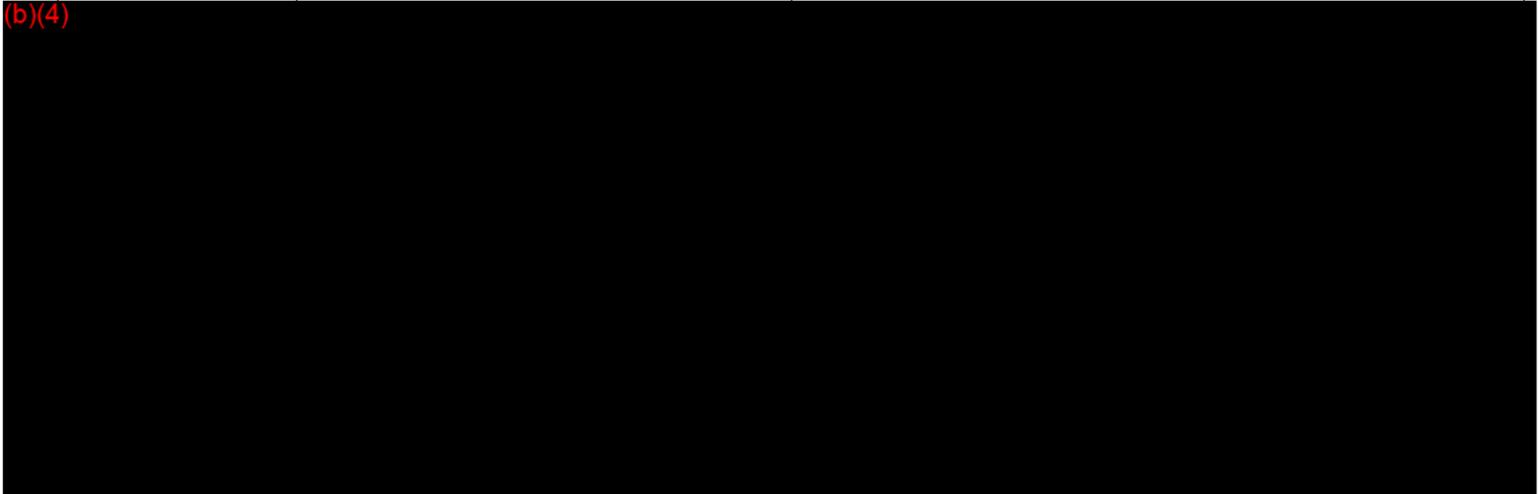
**SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number (b)(4)	<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 (b)(4)		
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 Director, Plant Quality		Contact E-mail Address (b)(4)

<input checked="" type="checkbox"/> Original	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer	<input checked="" type="checkbox"/> Contract Sterilizer
--	--	---------------------------------------	---



<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	
--	--	---	--



**SECTION I** Records processed under FOIA **UTILIZATION OF STANDARDS** based by CDRH on 02-01-2016

**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	03/01/2007
3	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
4	10993-7	AAMI ANSI ISO	ISO 10993-7:2008, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals	2008	12/10/2008
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

**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.



25 October 2013

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

**Re: Traditional 510(k) Premarket Notification:**

**Ethicon Endo-Surgery HARMONIC FOCUS® Shears + Adaptive Tissue Technology**

Dear Sir or Madam:

Pursuant to 21 CFR 807.90, Ethicon Endo-Surgery is submitting two copies of this traditional 510(k) premarket notification for the Ethicon Endo-Surgery Harmonic Focus Shears + Adaptive Tissue Technology. The design of the new device is based upon the predicate device Harmonic Focus Shears, cleared under K100597 on 07 April 2010.

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

Submission Type:	Traditional 510(k)
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: <a href="mailto:bgodwin@its.jnj.com">bgodwin@its.jnj.com</a>

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	K100597

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

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

Payment of the user fee has been made. A unique payment identification number (PIN) has been assigned to this submission, it is MD6071002-956733. 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. The electronic copy is accompanied by extra copies of the 510(k) cover letter and the 510(k) truthful and accuracy statement with original signatures.

If there are any questions concerning this notification, please contact me at (513) 337-3623 or by email at [bgodwin@its.inj.com](mailto:bgodwin@its.inj.com). If I am not available, the alternate contact person for this submission is (b)(6)

(b)(6) (b)(4)

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on last page.

## Indications for Use

510(k) Number (if known)

Device Name

HARMONIC FOCUS® Shears +Adaptive Tissue Technology

Indications for Use (Describe)

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.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

**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** 25 October 2013

### Device Name

Trade Name: HARMONIC FOCUS Shears + Adaptive Tissue Technology  
Common Name: Instrument, Ultrasonic Surgical

### Classification Name

Instrument, Ultrasonic Surgical (Unassigned, Product Code LFL)

### Predicate Device

HARMONIC FOCUS® Shears, cleared under K100597 on 07 April 2010

### Device Description

The Ethicon Endo-Surgery HARMONIC FOCUS Shears + Adaptive Tissue Technology is a sterile, single-patient use surgical 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's working length is 9 cm in length with a 16 mm active blade length. The instrument allows for the cutting and coagulation of vessels up to and including 5 mm in diameter.

### Indications for Use

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.

### **Technological Characteristics**

The HARMONIC FOCUS Shears + Adaptive Tissue Technology use an EEPROM memory chip that stores device identification, usage tracking, and operating parameters for use by the Generator G11 that provides power for the HARMONIC FOCUS Shears + Adaptive Tissue Technology. Adaptive Tissue Technology refers to the power output algorithm that is utilized by the devices. During use, the Adaptive Tissue Technology algorithm parameters stored on the device EEPROM are read by the generator and used to reduce the power (current) to the instrument and provide a secondary, higher pitched generator activation tone as Adaptive Tissue Technology regulates the delivery of energy. To do this the generator monitors the thermal condition of the blade during device activation.

### **Performance Data**

Bench testing and laboratory evaluations in an animal model including acute and 30-day chronic survival studies were conducted to demonstrate that the HARMONIC FOCUS Shears + Adaptive Tissue Technology perform as intended.

### **Conclusion**

The results of the bench testing and laboratory evaluations in an animal model demonstrate that the HARMONIC FOCUS 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.

### 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 related to a substantial equivalence decision has been omitted.



---

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

25 OCT 2013

Date

### **Section 7: Class III Summary and Certification**

This section does not apply; the Ethicon Endo-Surgery HARMONIC FOCUS Shears + Adaptive Tissue Technology are Class II devices.

### **Section 8: Financial Certification or Disclosure Statement**

This section does not apply; no clinical studies were performed to support this submission.

### **Section 9: Declarations of Conformity and Summary Reports**

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

## Section 10: Executive Summary

The purpose of this premarket 510(k) submission is to notify the FDA of the intent to commercialize the Ethicon Endo-Surgery HARMONIC FOCUS Shears + Adaptive Tissue Technology. The following surgical instrument has been identified as a predicate for the purposes of this submission:

- HARMONIC FOCUS Shears (FCS9), cleared under K100579 on 07 April 2010

It is the intent of this submission to demonstrate substantial equivalence of the HARMONIC FOCUS Shears + Adaptive Tissue Technology to the above-mentioned predicate surgical instrument.

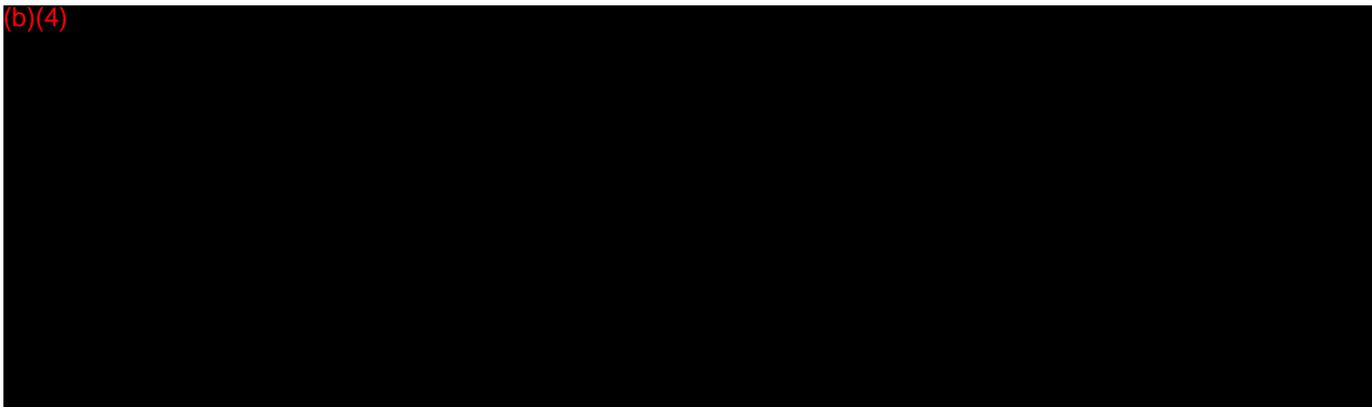
This subject device has never been submitted to the FDA before. There are no prior 510k submissions for the subject device. This is a new 510(k) submission.

### Device Description

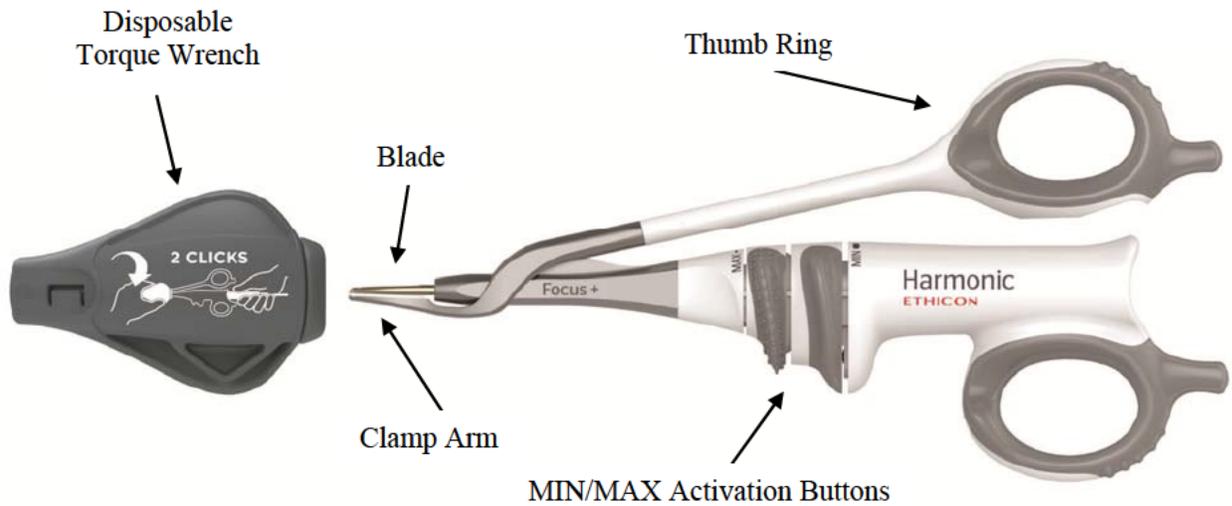
The HARMONIC FOCUS Shears + Adaptive Tissue Technology are sterile, single-patient use surgical instruments designed to cut and seal vessels up to and including 5 mm in diameter, and to cut, grasp, and dissect tissue during open surgery. Coagulation is achieved with a blade that vibrates at ultrasonic frequencies, providing mechanical energy to the tissue. A pivoting clamp arm opens and closes to supply compression to targeted tissue.

The devices have a soft grip scissor handle housing assembly with two hand controls (MIN for minimum power level and MAX for maximum power level) located on the bottom of the device. 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. The instrument has a curved blade and clamp arm with a teflon pad. The instrument has a 9 cm working length with a 16 mm active blade length. Each HARMONIC FOCUS Shears + Adaptive Tissue Technology instrument is packaged with one sterile, single-patient use, disposable gray torque wrench.

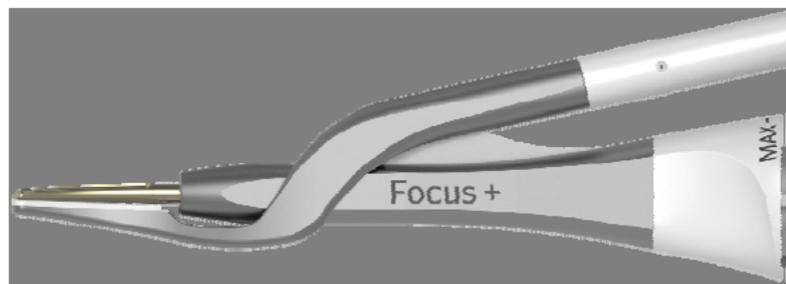
(b)(4)



Figures 10-1 and 10-2 provide representative images of the device that is the subject of this submission. The page following these figures presents a dimensional engineering drawing.



**Figure 10-1: HARMONIC FOCUS Shears + Adaptive Tissue Technology**



**Figure 10-2: HARMONIC FOCUS Shears + Adaptive Tissue Technology – End Effector**



Tables 10-1 through 10-3 contain comparisons between the subject and predicate device with respect to indications/contraindications, technology and performance specifications, and patient contacting materials, respectively.

**Table 10-1: Device Comparison Table – Indications for Use and Contraindications**

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

(b)(4)



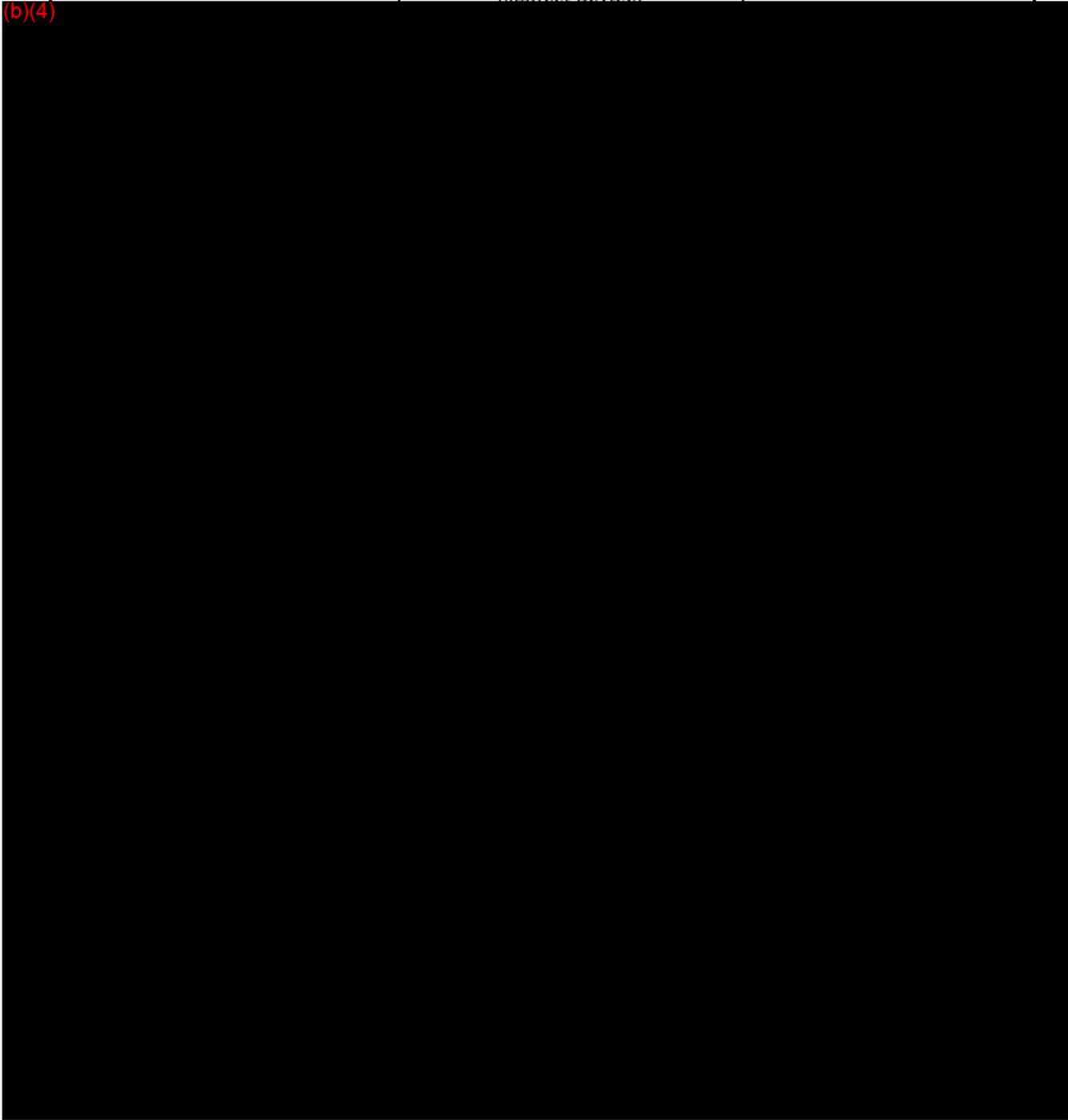
**Table 10-2: Device Comparison Table – Technology and Performance Specifications**

Device Characteristic	HARMONIC FOCUS Shears + Adaptive Tissue Technology <i>(subject device)</i>	HARMONIC FOCUS <i>(predicate device)</i>
(b)(4)		FCS9
		Same
		(b)(4)
		(b)(4)
		Same
	(b)(4)	
	(b)(4)	
	Same	
(b)(4)		

**Table 10-3: Device Comparison Table – Patient Contact Materials**

<b>Component</b>	<b>HARMONIC FOCUS Shears + Adaptive Tissue Technology</b> <i>(subject device)</i>	<b>HARMONIC FOCUS</b> <i>(predicate device)</i>
------------------	--	--

(b)(4)



### Performance Testing

The following bench and animal performance testing was completed to support a substantial equivalence determination for the HARMONIC FOCUS Shears + Adaptive Tissue Technology to the referenced predicate device. (b)(4)

(b)(4)

Additional details with respect to the test methods and acceptance criteria are contained in the performance testing sections of this submission.

(b)(4)

## Section 11: Device Description

### Device Design and Principles of Operation

The HARMONIC FOCUS Shears + Adaptive Tissue Technology are sterile, single-patient use surgical instruments designed to cut and seal vessels up to and including 5 mm in diameter, and to cut, grasp, and dissect tissue during open surgery. (b)(4)

(b)(4) A pivoting clamp arm opens and closes to supply compression to targeted tissue.

The devices have a soft grip scissor handle housing assembly with two hand controls (MIN for minimum power level and MAX for maximum power level) located on the bottom of the device. 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. The instrument has a curved blade and clamp arm with teflon pad. The instrument has a 9 cm working length with a 16 mm active blade length. Each HARMONIC FOCUS Shears + Adaptive Tissue Technology instrument is packaged with one sterile, single-patient use, disposable gray torque wrench.

(b)(4)

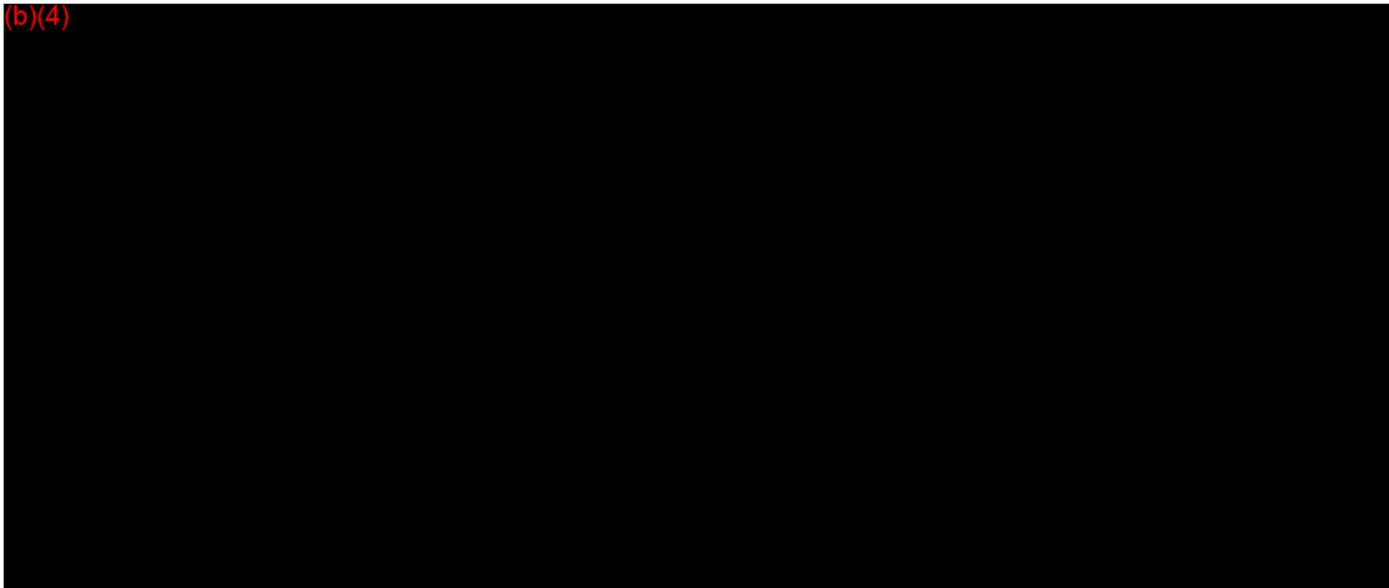


Table 11-1 contains the full name and product code for the device that is the subject of this 510(k) submission.

**Table 11-1: HARMONIC FOCUS Shears + Adaptive Tissue Technology – Product Code and Full Name**

Product Code	Device Full Name
HAR9F	HARMONIC FOCUS® Shears + Adaptive Tissue Technology

Table 11-2 contains a summary of device characteristics and specifications for the HARMONIC Focus Shears + Adaptive Tissue Technology.

**Table 11-2: HARMONIC FOCUS Shears + Adaptive Tissue Technology – Device Characteristics and Specifications**

Characteristic	Specification
----------------	---------------

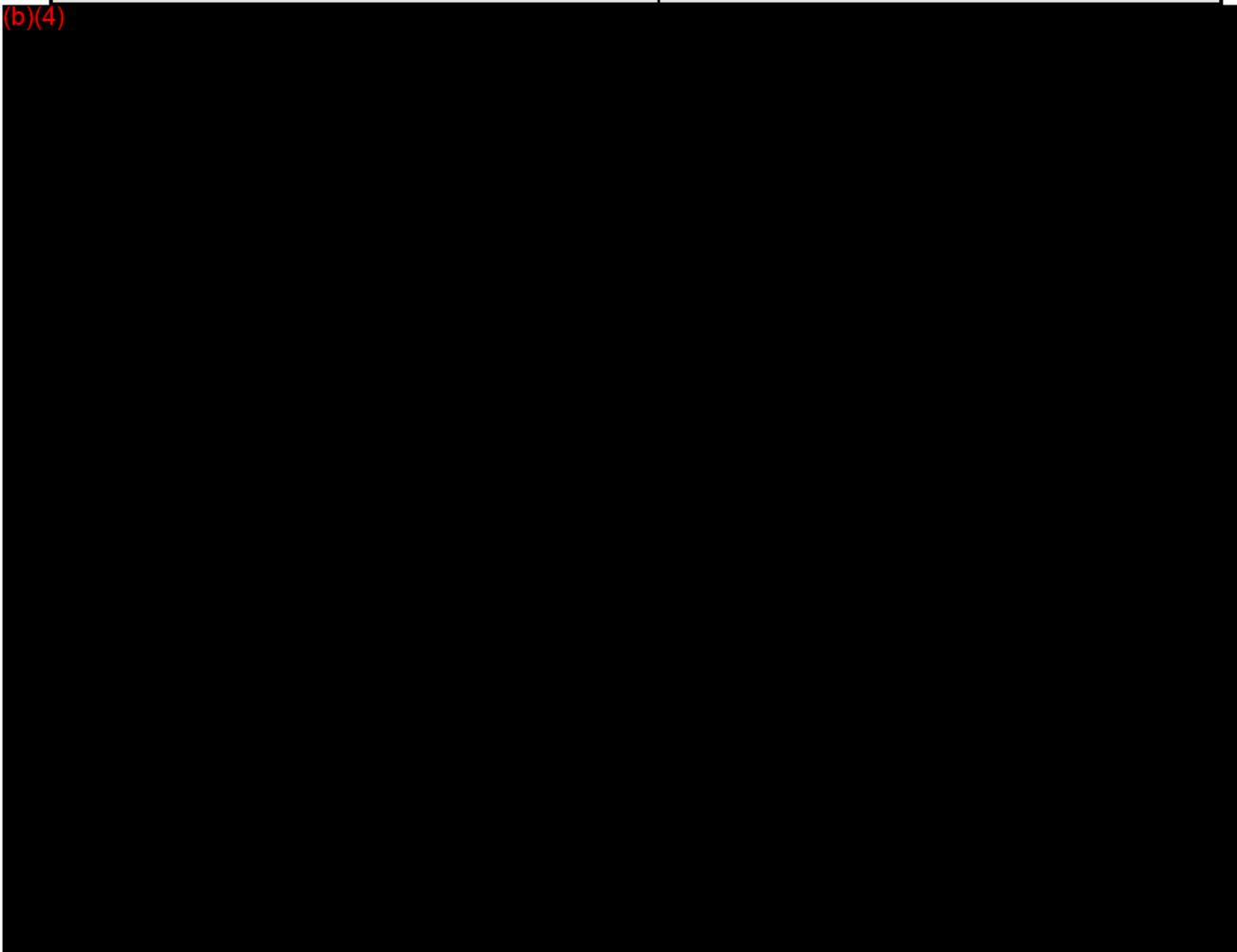
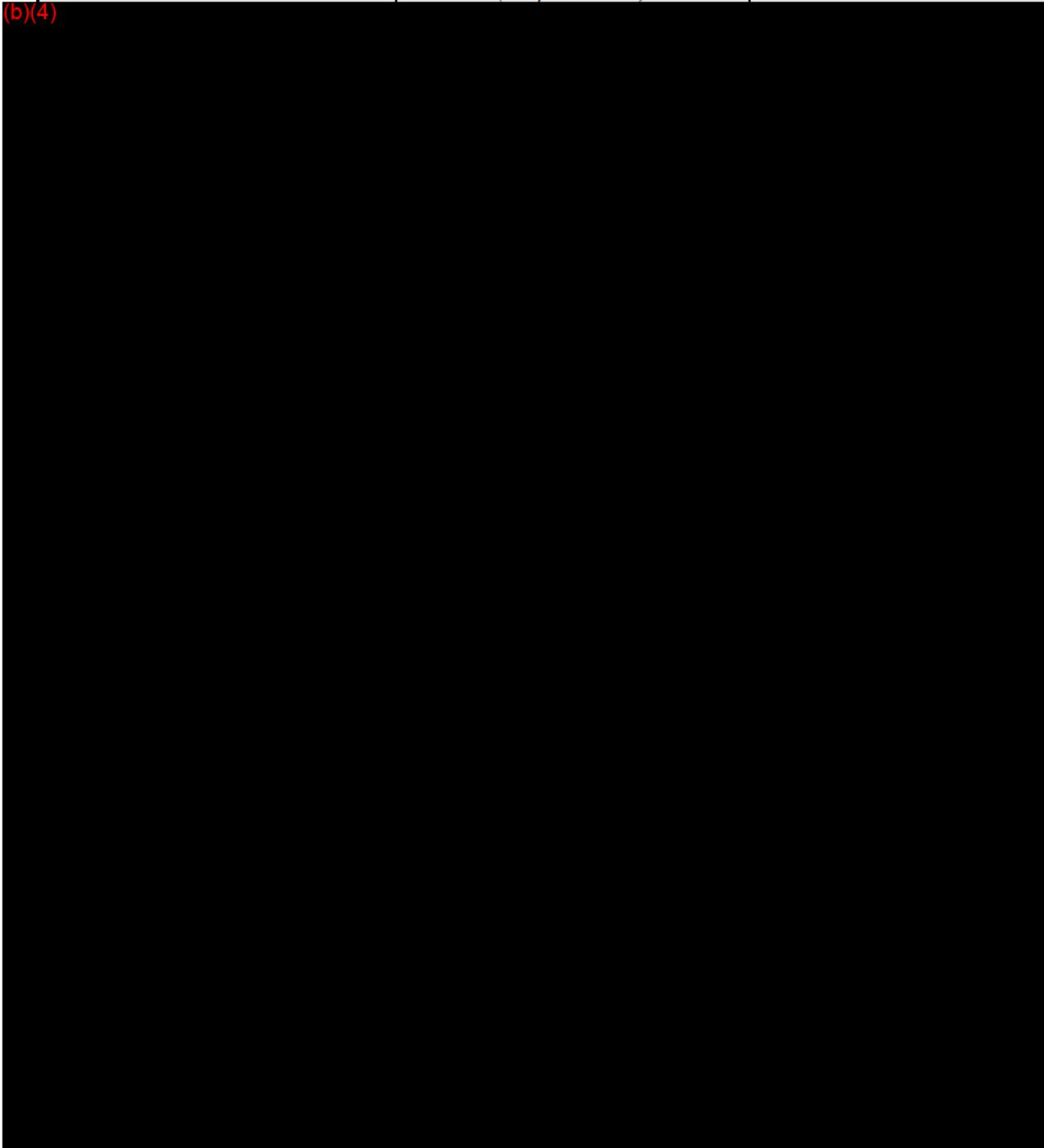


Table 11-3 presents the patient contacting materials of the HARMONIC FOCUS Shears + Adaptive Tissue Technology.

**Table 11-3: HARMONIC FOCUS Shears + Adaptive Tissue Technology  
Patient Contacting Materials**

Component	HARMONIC FOCUS Shears + Adaptive Tissue Technology <i>(subject device)</i>	HARMONIC FOCUS <i>(predicate device)</i>
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## Section 12: Substantial Equivalence Discussion

Ethicon Endo-Surgery HARMONIC FOCUS Shears + Adaptive Tissue Technology are compared to the following predicate devices:

- HARMONIC FOCUS Shears, cleared under K100597 on 07 April 2010

The predicate devices referenced for this 510(k) are manufactured by Ethicon Endo-Surgery, LLC. The *510(k) Substantial Equivalence Decision Making Process (Detailed) Decision Tree (Blue Book Memorandum K86-3, 1986)* was used in determining substantial equivalence of the Ethicon Endo-Surgery HARMONIC FOCUS Shears + Adaptive Tissue Technology to the referenced predicate device. The decision-making flowchart with the path applicable to this submission highlighted in yellow from which the following questions with respect to substantial equivalence listed in this section were selected is provided as Figure 12-1.

**Does the new device have same indications statement?**

(b)(4)

**Does new device have same indication statement?**

(b)(4)

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

(b)(4)

**Could the new characteristics affect safety or effectiveness?**

(b)(4)

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

(b)(4)

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

(b)(4)

**Are performance data available to assess effects of new characteristics?**

(b)(4)

**Performance data demonstrate equivalence?**

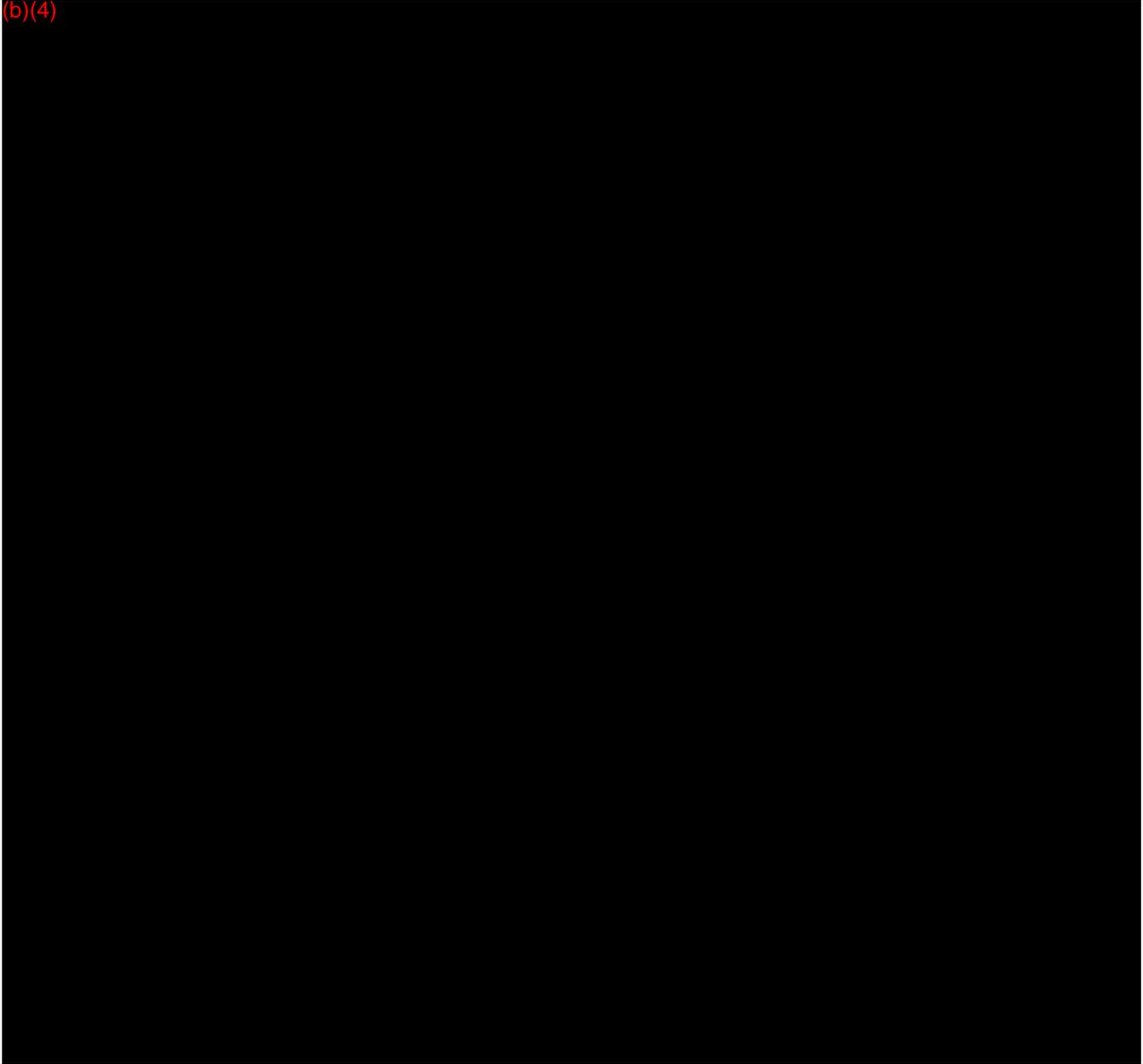
(b)(4) [Redacted]

**Conclusion**

(b)(4) [Redacted]

**Figure 12-1**  
**510(k) Substantial Equivalence Decision Making Process (Detailed) Decision Tree**  
**(Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3))**

(b)(4)



\* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and “predicate” devices is unclear.

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

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

25 October 2013  
Confidential

35

Tables 12-1 through 12-4 contain comparisons between the subject and predicate devices with respect to indications/contraindications, technology and performance specifications, patient contacting materials, and external non-patient contacting materials, respectively.

**Table 12-1: Device Comparison Table, Indications for Use and Contraindications**

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

(b)(4)



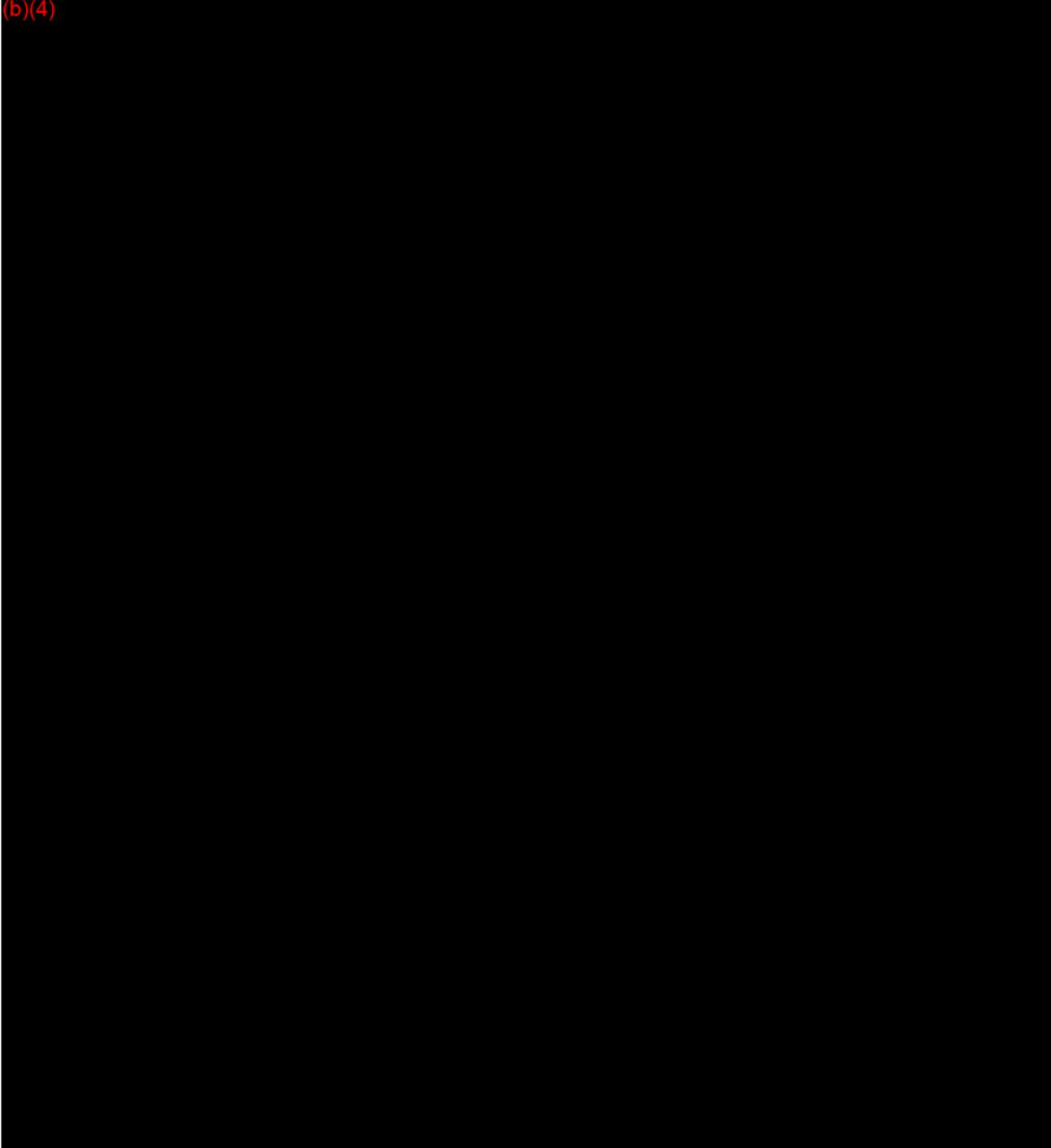
**Table 12-2: Device Comparison Table – Technology, and Performance Specifications**

Device Characteristic	HARMONIC FOCUS Shears + Adaptive Tissue Technology <i>(subject device)</i>	HARMONIC FOCUS <i>(predicate device)</i>
(b)(4)		

**Table 12-3: Device Comparison Table – Patient Contact Materials**

<b>Component</b>	<b>HARMONIC FOCUS Shears + Adaptive Tissue Technology</b> <i>(subject device)</i>	<b>HARMONIC FOCUS</b> <i>(predicate device)</i>
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(b)(4)



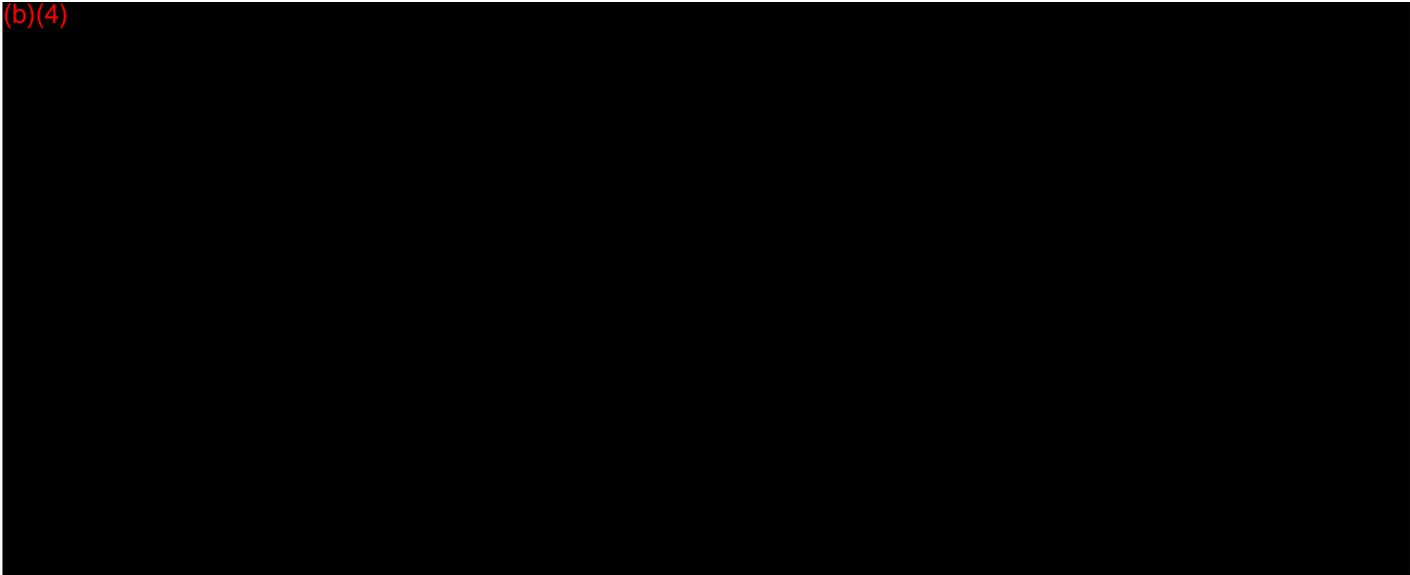
## Performance Testing Summary

The following is a brief summary of the bench and animal performance testing that was performed to support substantial equivalence of the HARMONIC FOCUS Shears + with Adaptive Tissue Technology to the referenced predicate device. Additional details concerning the test methods and acceptance criteria are contained in the respective performance testing sections of this submission.

(b)(4)



(b)(4)



*Conclusion*

The results of the bench and animal testing performed demonstrate that the HARMONIC FOCUS Shears + Adaptive Tissue Technology are substantially equivalent to the identified predicate device.

### **Section 13: Proposed Labeling**

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

The labeling contained in this section includes:

- Figure 13-1 Draft Tyvek Label
- Figure 13-2 Draft Carton Label
- Draft Instructions for Use

<b>Harmonic</b>	<b>ETHICON</b>		
<b>FOCUS® Shears</b>	<b>+ Adaptive Tissue Technology</b>	<b>9 cm Length</b>	REF ① <b>HAR9F</b>

HARMONIC FOCUS® Shears, 9 cm Length, +Adaptive Tissue Technology  
 HARMONIC FOCUS® Shears, 9 cm Length, +Adaptive Tissue Technology  
 HARMONIC FOCUS® Shears, 9 cm Length, +Adaptive Tissue Technology  
 HARMONIC FOCUS® Shears, 9 cm Length, +Adaptive Tissue Technology  
 HARMONIC FOCUS® Shears, 9 cm Length, +Adaptive Tissue Technology  
 HARMONIC FOCUS® Shears, 9 cm Length, +Adaptive Tissue Technology  
 HARMONIC FOCUS® Shears, 9 cm Length, +Adaptive Tissue Technology  
 HARMONIC FOCUS® Shears, 9 cm Length, +Adaptive Tissue Technology  
 HARMONIC FOCUS® Shears, 9 cm Length, +Adaptive Tissue Technology

**STERILE** Sterilized by EO.  
 Sterility Guaranteed Unless Package Opened or  
 Damaged. Do Not Resterilize.

**Single Patient Use**     **See Instructions For Use**

**CAUTION: US Federal Law restricts this device to  
 sale by or on the order of a physician.**

ETHICON ENDO-SURGERY, LLC     ©EES, LLC 2013  
 475 Calle C  
 Guaynabo, Puerto Rico 00969 USA     Assembled in Mexico

**For Use with  
BLUE Hand Piece ONLY**

ULTRACISION  
 GENERATOR  
 (GEN01) (GEN32)  
 (GEN04)

A95531P00

Figure 13-1: Draft Tyvek Label – HAR9F

**ETHICON**



**Harmonic**

**Focus® Shears**

**+ Adaptive Tissue Technology**

**9 cm Length**

**REF HAR9F**



HARMONIC FOCUS® Shears, 9 cm Length, +Adaptive Tissue Technology  
HARMONIC FOCUS® Shears, 9 cm Length, +Adaptive Tissue Technology  
HARMONIC FOCUS® Shears, 9 cm Length, +Adaptive Tissue Technology  
HARMONIC FOCUS® Shears, 9 cm Length, +Adaptive Tissue Technology  
HARMONIC FOCUS® Shears, 9 cm Length, +Adaptive Tissue Technology  
HARMONIC FOCUS® Shears, 9 cm Length, +Adaptive Tissue Technology  
HARMONIC FOCUS® Shears, 9 cm Length, +Adaptive Tissue Technology  
HARMONIC FOCUS® Shears, 9 cm Length, +Adaptive Tissue Technology

**STERILE** Sterilized by EO. Sterility Guaranteed Unless Package Opened or Damaged. Do Not Re-sterilize.

**2** Single Patient Use  See Instructions For Use

**Rx Only** CAUTION: US Federal Law restricts this device to sale by or on the order of a physician.

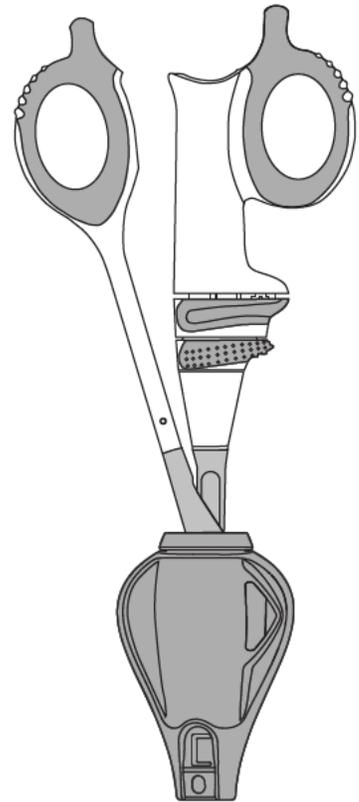
ETHICON ENDO-SURGERY, LLC ©EES, LLC 2013  
475 Calle C  
Guaynabo, Puerto Rico 00989 USA

**For Use with BLUE Hand Piece ONLY**

**Figure 13-2: Draft Carton – HAR9F**

# ETHICON

HARMONIC FOCUS® Shears + Adaptive Tissue Technology  
HARMONIC FOCUS® Shears + Adaptive Tissue Technology



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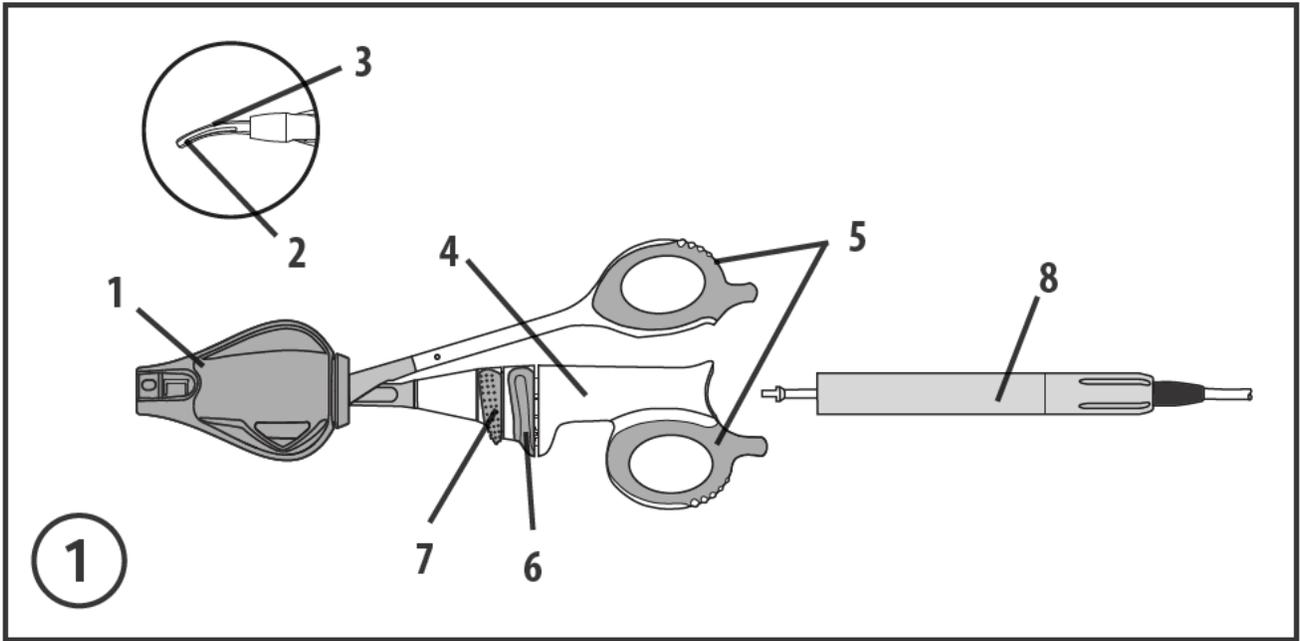
**Please read all information carefully.**

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

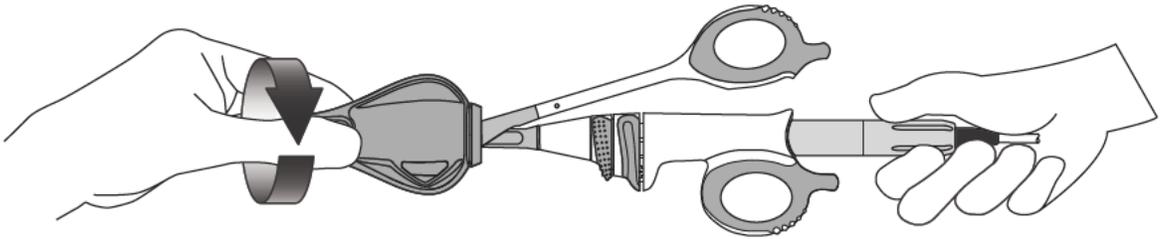
**Important:** This package insert is designed to provide instructions for use of the HARMONIC FOCUS® Shears + Adaptive Tissue Technology. It is not a reference to ligation techniques.

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

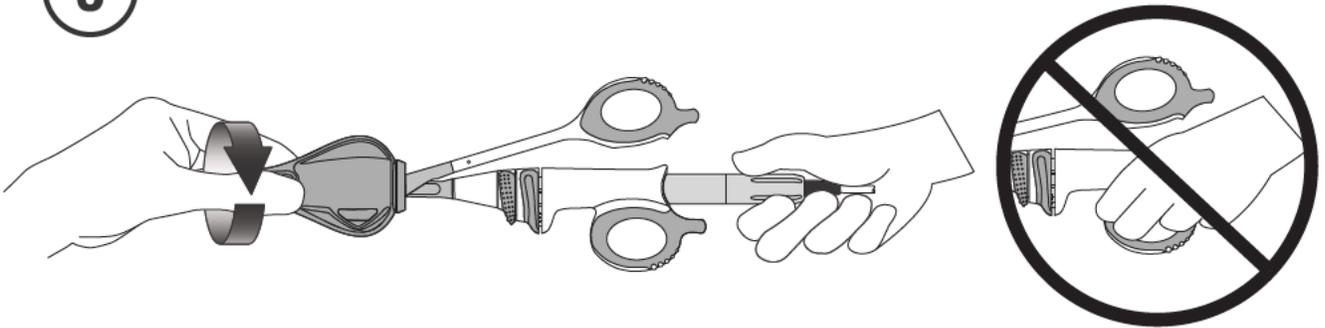
**Instructions, Instructions, Gebrauchsanweisung, Istruzioni, Instruções, Instrucciones, Gebruiksaanwijzing, Brugsvejledning, Ohje, Οδηγίες, Bruksanvisning, Instrukcja, Utasítások, Návod k použití, Návod, 使用说明**



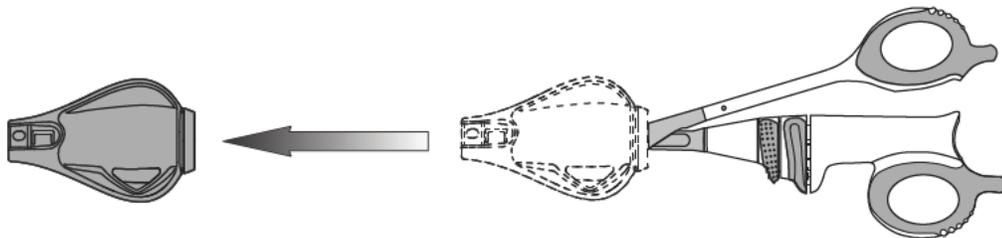
2



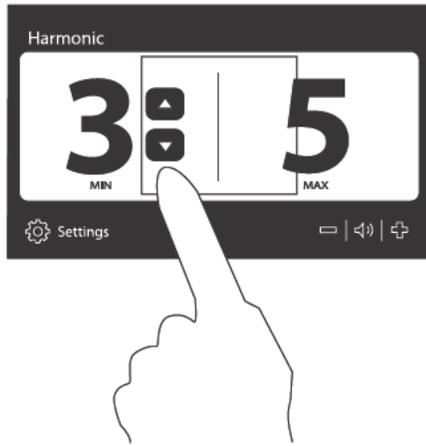
3



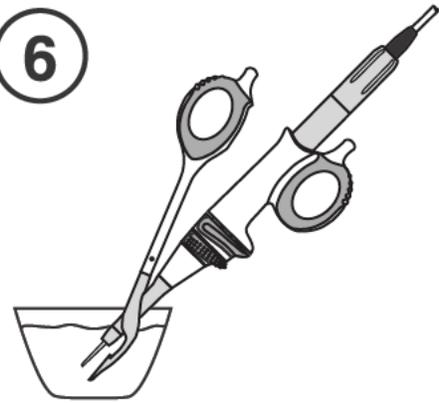
4



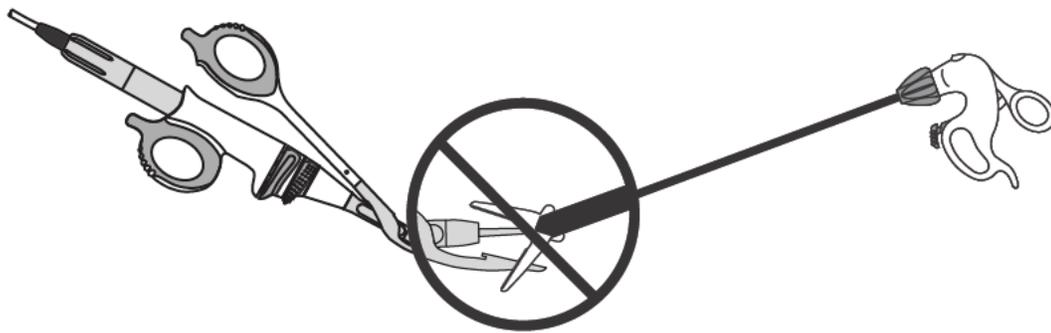
5



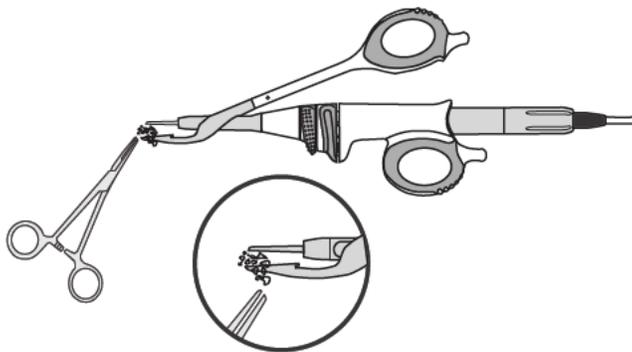
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### **Indications**

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 electro-surgical 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<sup>®</sup>+ 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.
- Minimum starting power level defaults to power level 3.
- Successful hemostasis may require adjunct measures when HARMONIC FOCUS<sup>®</sup>+ 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<sup>®</sup>+ 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<sup>®</sup>+ 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<sup>®</sup>+ 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<sup>®</sup>+ Shears instrument allows for the cutting and coagulation of vessels up to and including 5 mm in diameter.

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

- 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 betjeningsvejledningen (der henvises 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 zewnętrznym opakowaniu).                  Lásd a használati útmutatót (lásd a külső csomagoláson található kék szimbólumot).                  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).</p> <p>.....</p>
	<p>Relative Humidity                  Humidité relative                  Relative Feuchte                  Umidità relativa                  Humidade relativa                  Humedad relativa                  Relativ fugtighed                  Relativ fugtighed                  Suhteellinen kosteus                  Σχετική υγρασία                  Relativ fuktighet                  Wilgotność względna                  Relatív páratartalom                  Relativní vlhkost                  Relatívna vlhkosť</p> <p>.....</p>
	<p>Temperature                  Température                  Temperatur                  Temperatura                  Temperatura                  Temperatura                  Temperatur                  Temperatur                  Lämpötila                  Θερμοκρασία                  Temperatur                  Temperatura                  Hőmérséklet                  Teplota                  Teplota</p> <p>.....</p>



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



<p><b>For Use with BLUE Hand Piece ONLY</b></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.          只可与蓝色手柄配合使用。</p>
	<p>Dispose of properly.          Éliminer de façon appropriée.          Ordnungsgemäß entsorgen.          Eliminare a norma.          Elimine correctamente.          Desechar adecuadamente.          Op de geschikte wijze afvoeren.          Bortskaffes på korrekt vis.          Hävitä asianmukaisesti.          Απορρίψτε με τον ενδεδειγμένο τρόπο.          Kassera på lämpligt sätt.          Usunąć w odpowiedni sposób.          Megfelelő módon helyezze hulladékba.          Zlikvidujte předepsaným způsobem.          Riadne zlikvidujte.          妥善废弃。</p>

**STERILE EO**

Sterilized by EO.  
 Sterility Guaranteed Unless Package Opened or Damaged. Do Not Resterilize.  
 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 resterilisieren.  
 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 ethylenoxide.  
 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 zaručená, ak nie je otvorený alebo poškodený obal. Neresterilizujte.

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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</p>	<p>Til anvendelse på én patient          Potilaskohtainen          Χρήση σε έναν μόνον ασθενή          Endast för en patients bruk          Do użytku u jednego pacjenta          Egyetlen betegnél használható fel          Nástroj je určený pouze pro jednoho pacienta          Určené iba pre jedného pacienta          单个患者使用</p>
	<p>Lot          N° de lot          Ch.-B.          Lotto          N° do lote          N° de lote          Lotnr.          Parti</p>	<p>Erän koodi          Αρ. παρτίδας          Batchnummer          Numer partii produkcyjnej          Tétel          Šarže          Šarža          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</p>	<p>Käytettävä viimeistään          Χρησιμοποιείτε μέχρι την          Använd före          Koniec okresu przydatności do użytku          A feltüntetett dátumig használható fel          Použit do data          Použitelné do          有效期</p>
	<p>Manufacturer/Date of Manufacture          Fabricant          Hersteller          Fabbricante          Fabricante          Fabricante          Fabrikant          Producent</p>	<p>Valmistaja          Κατασκευαστής          Tillverkare          Producent          Gyártó          Výrobce          Výrobca          制造商</p>
	<p>Authorized Representative in the European Community          Représentant autorisé dans la Communauté européenne          Bevollmächtigter in der Europäischen Gemeinschaft          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>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>.....</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>.....</p>

REF  
HAR9F



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



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Cincinnati, OH 45242-2839 USA  
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# ETHICON



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**475 Calle C**  
**Guaynabo, PR 00969 USA**



Rev. 2013-XX

P40730P01

Questions? Contact FDA/CDRH/OCE/DID at [CDRH-FOISTATUS@fda.hhs.gov](mailto:CDRH-FOISTATUS@fda.hhs.gov) or 301-796-8118

REVISIONS			
LTR	CAF NO.	CHNG	DATE
A			
PRODUCT CODE	ARTWORK NUMBER	PACKAGE COMPONENT NUMBER	
HAR9F	A88459P00	P40730P01	



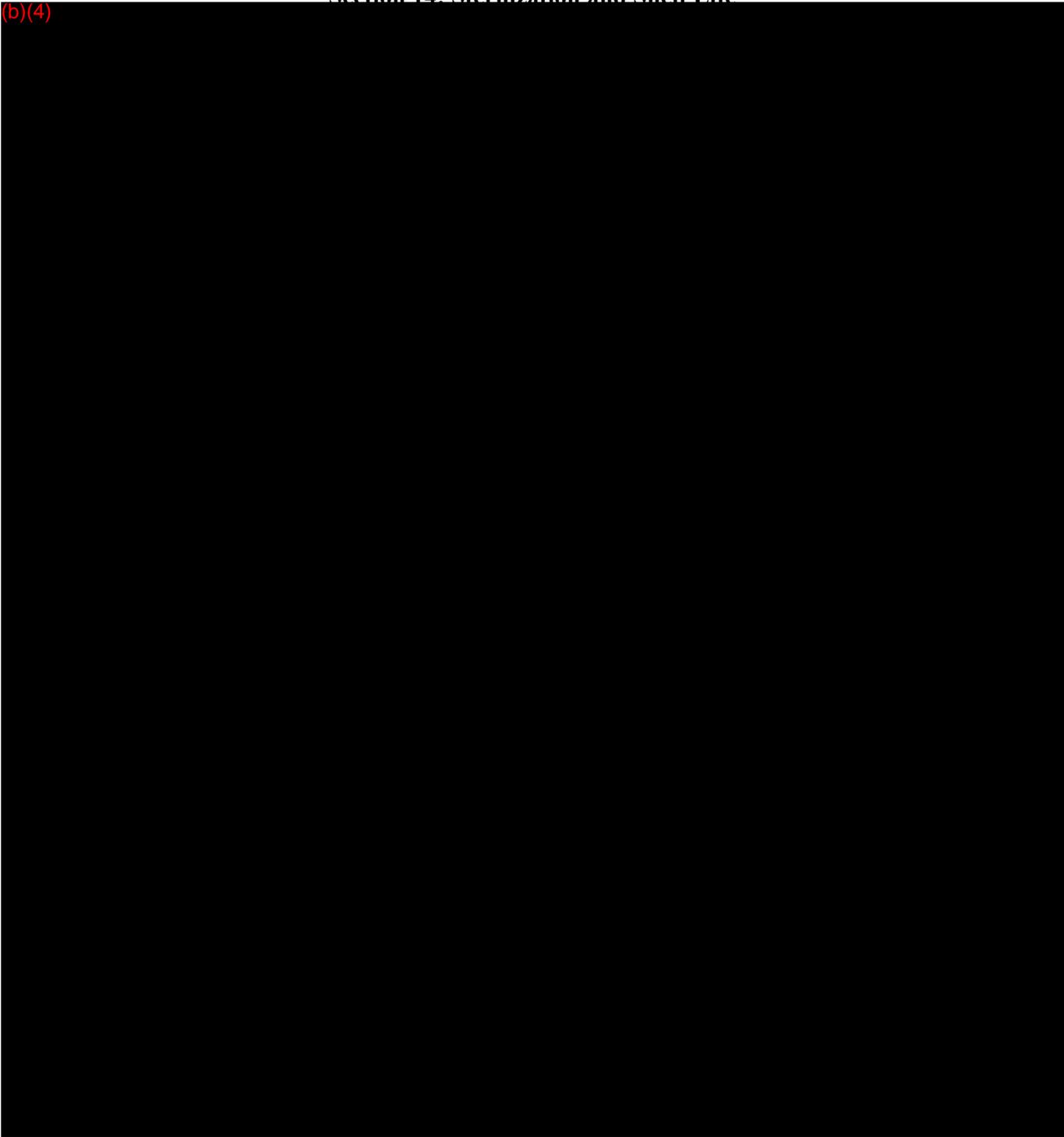
ETHICON ENDO-SURGERY, INC.

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ENDO-SURGERY, INC. APPROVAL. CINCINNATI, OH

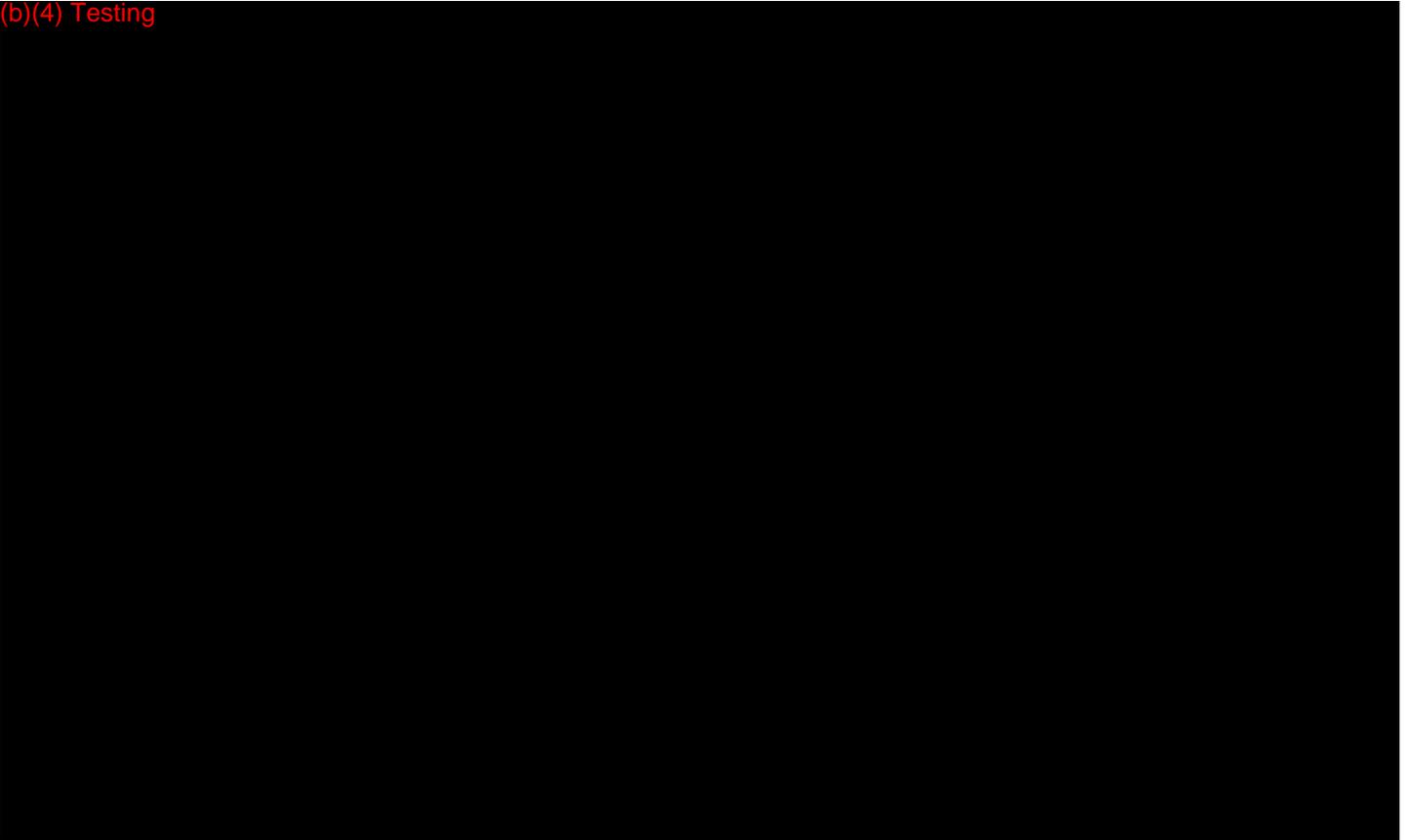
BLACK

**Section 14: Sterilization and Shelf Life**

(b)(4)



(b)(4) Testing



### Section 15: Biocompatibility

All patient contact materials referenced in Table 15-1 have the following contact categories as defined in ISO 10993-1:2009

Category: Externally Communicating Devices

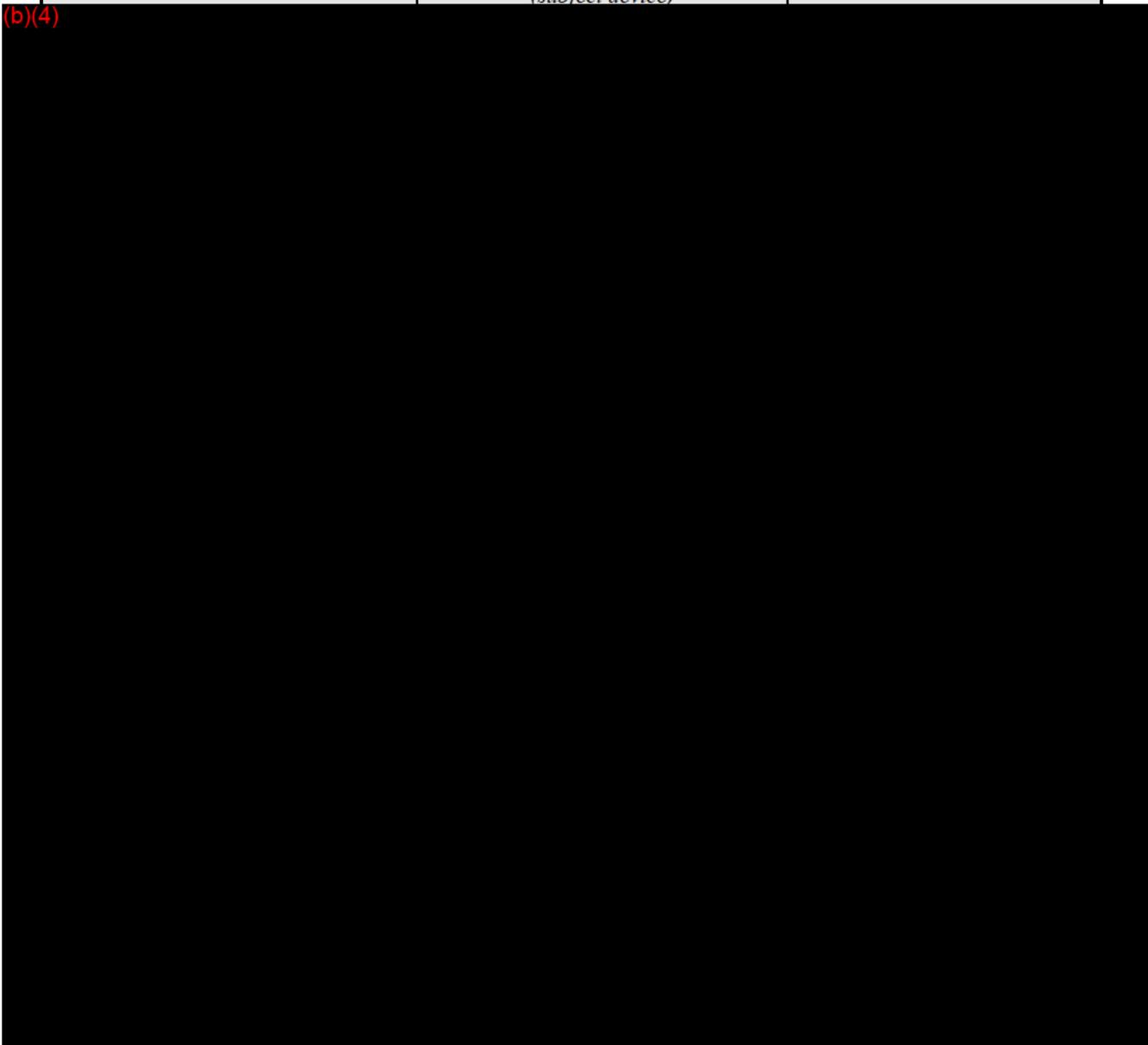
Contact: Tissue/Bone/Dentin

Contact Duration: Limited <24 hours

**Table 15-1: Device Comparison Table – Patient Tissue Contact Materials**

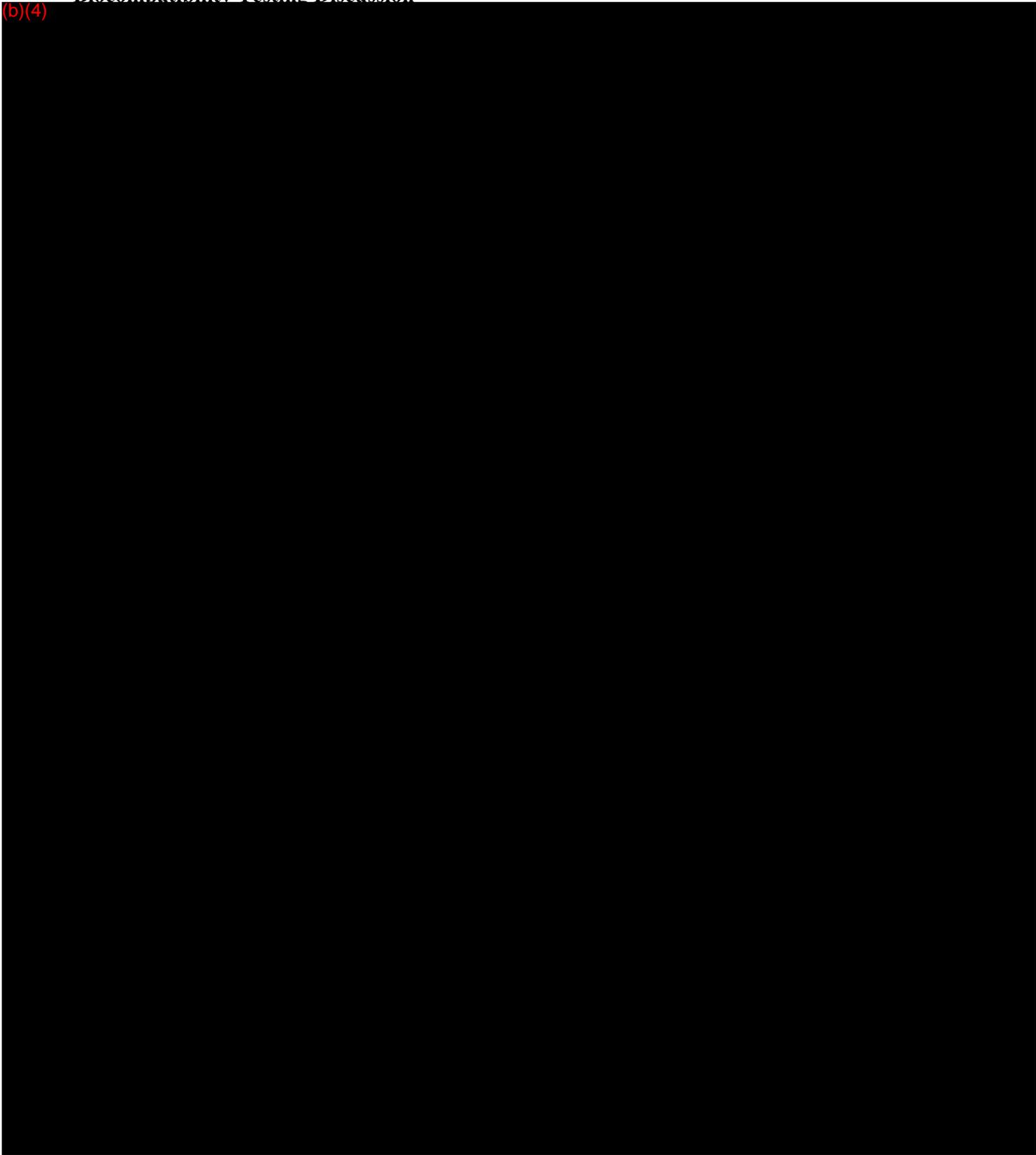
<b>Component</b>	<b>HARMONIC FOCUS Shears + Adaptive Tissue Technology</b> <i>(subject device)</i>	<b>HARMONIC FOCUS</b> <i>(predicate device)</i>
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(b)(4)

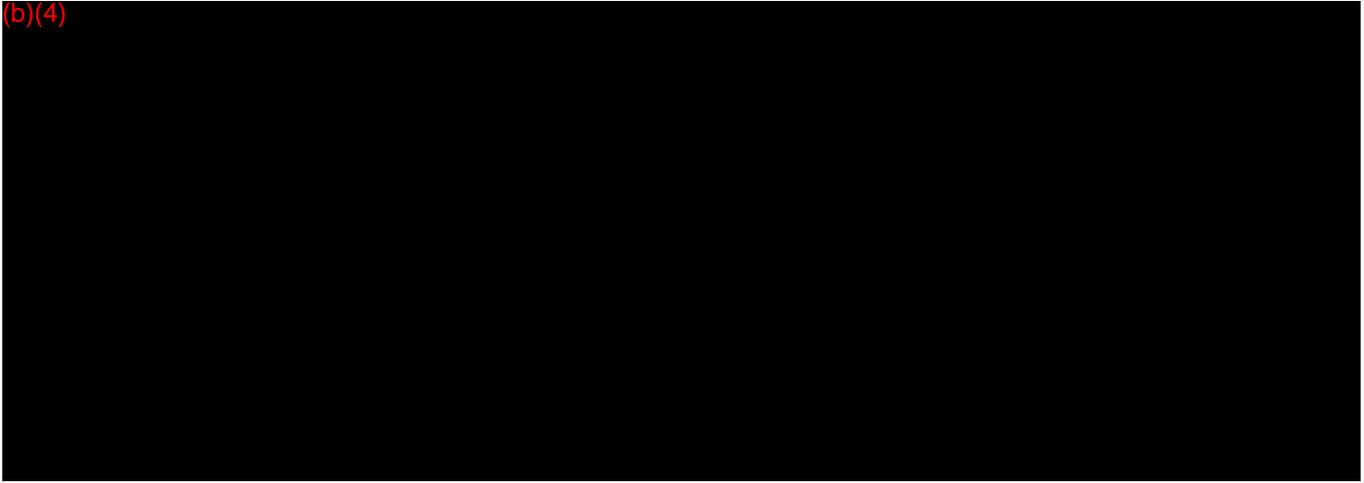


## Biocompatibility Testing Discussion

(b)(4)



(b)(4)



### **Section 16: Software**

This section does not apply; the subject device does not contain software.

## Section 17: Electromagnetic Compatibility and Electrical Safety

### Electromagnetic Compatibility

Testing to the following standard for Electromagnetic Compatibility was performed and subsequently certified for all applicable sections by the accredited testing facility listed below. An Extent of Standard Conformance Summary Report Table with respect to this standard is included in Section 22: Form FDA 3654 of this submission.

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 5-54)

Certification Facility:

(b)(4)



### Electrical Safety

Testing to the following standards for electrical safety was performed and subsequently certified for all applicable sections by the IECEE associated CB testing facility listed below. An Extent of Standard Conformance Summary Report Table with respect to this standard is included in Section 22: Form FDA 3654 of this submission.

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

Certification Facility:

(b)(4)



### Section 18: Performance Testing - Bench

The information presented in this section represents the bench testing used to evaluate and verify the performance of the HARMONIC FOCUS Shears + Adaptive Tissue Technology (HAR9F).

(b)(4)

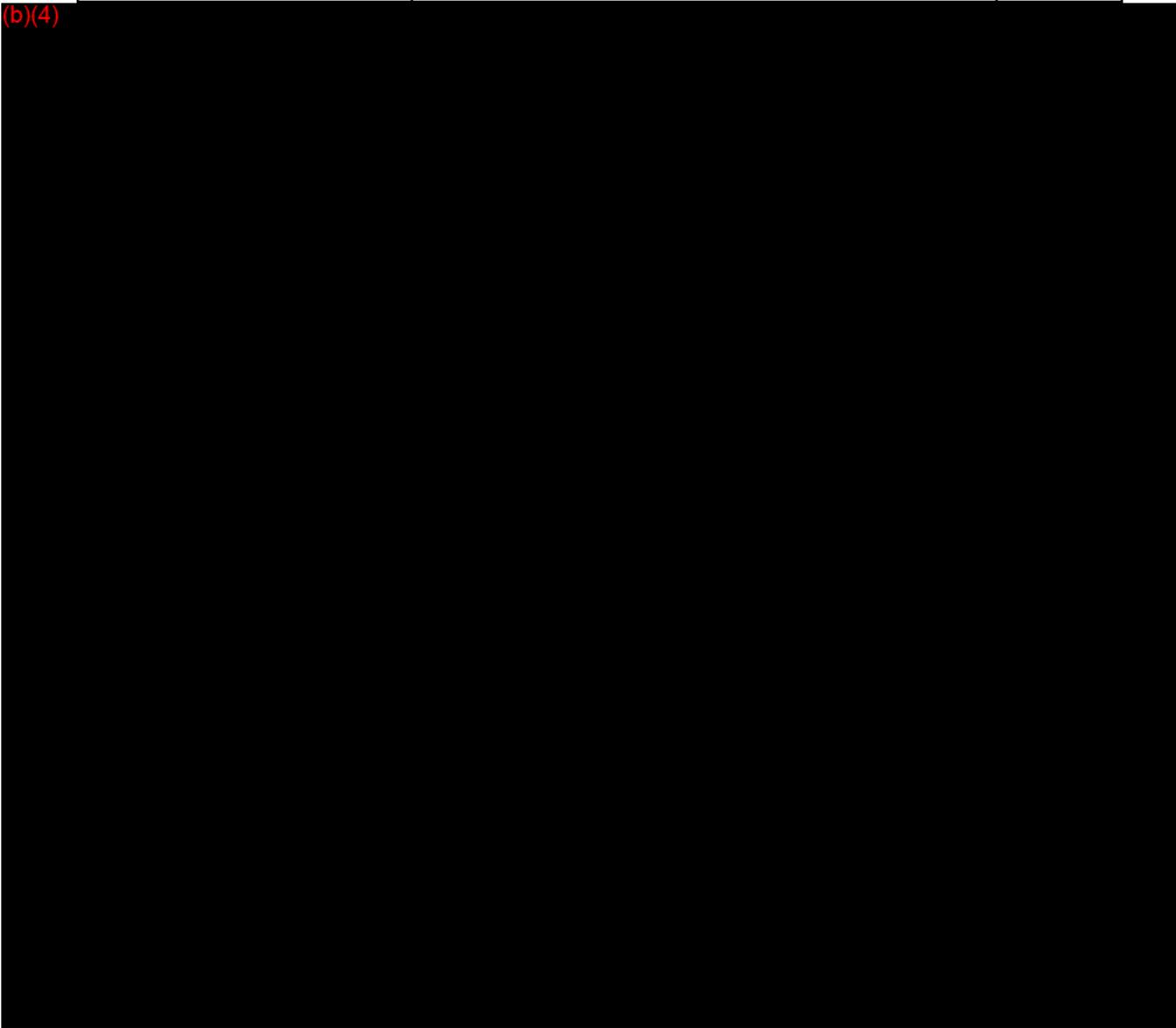


Table 18-1 provides a summary of the bench performance testing.

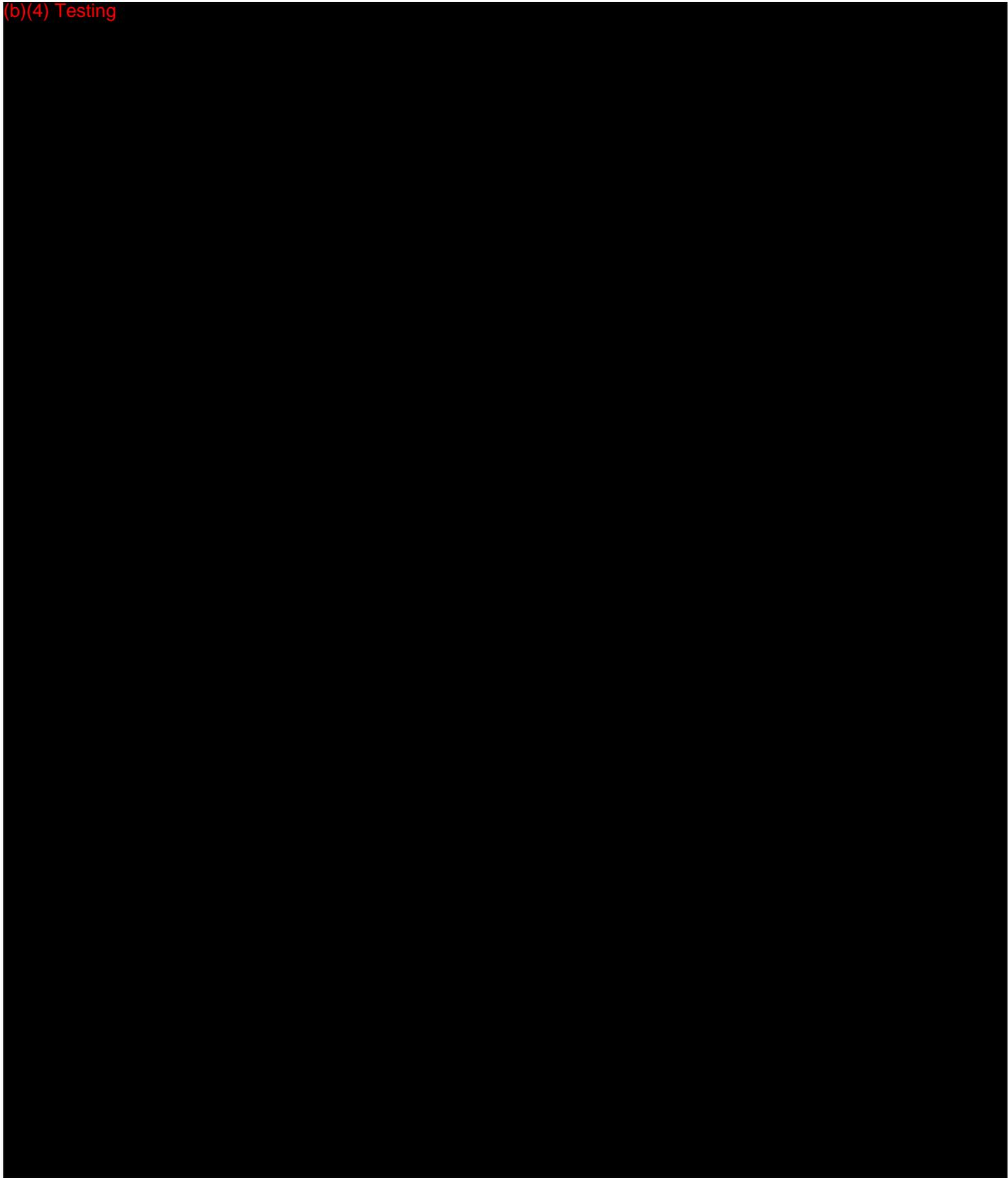
**Table 18-1: Bench Performance Tests and Results**

Performance Test	Objective	Result
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(b)(4)



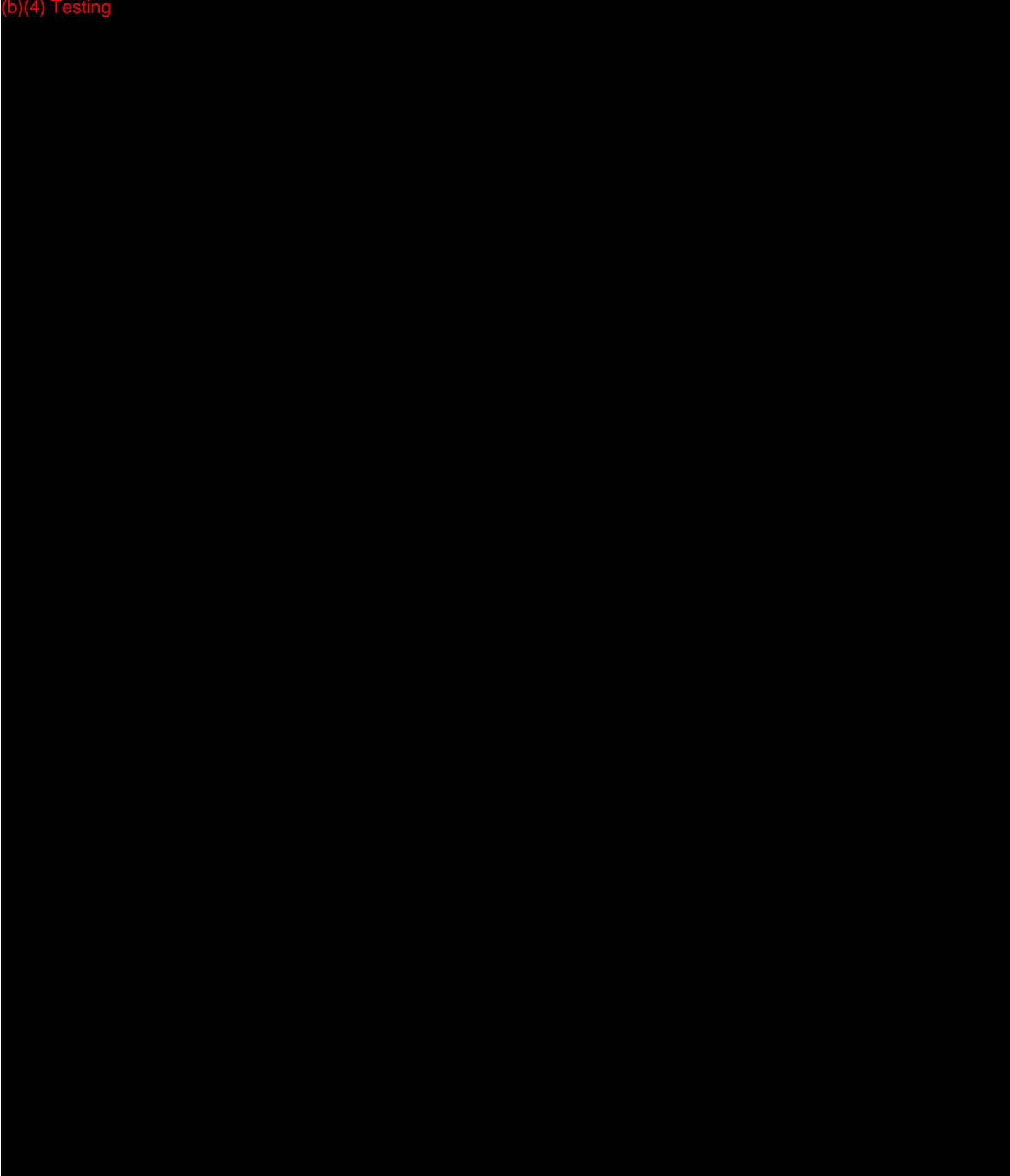
(b)(4) Testing



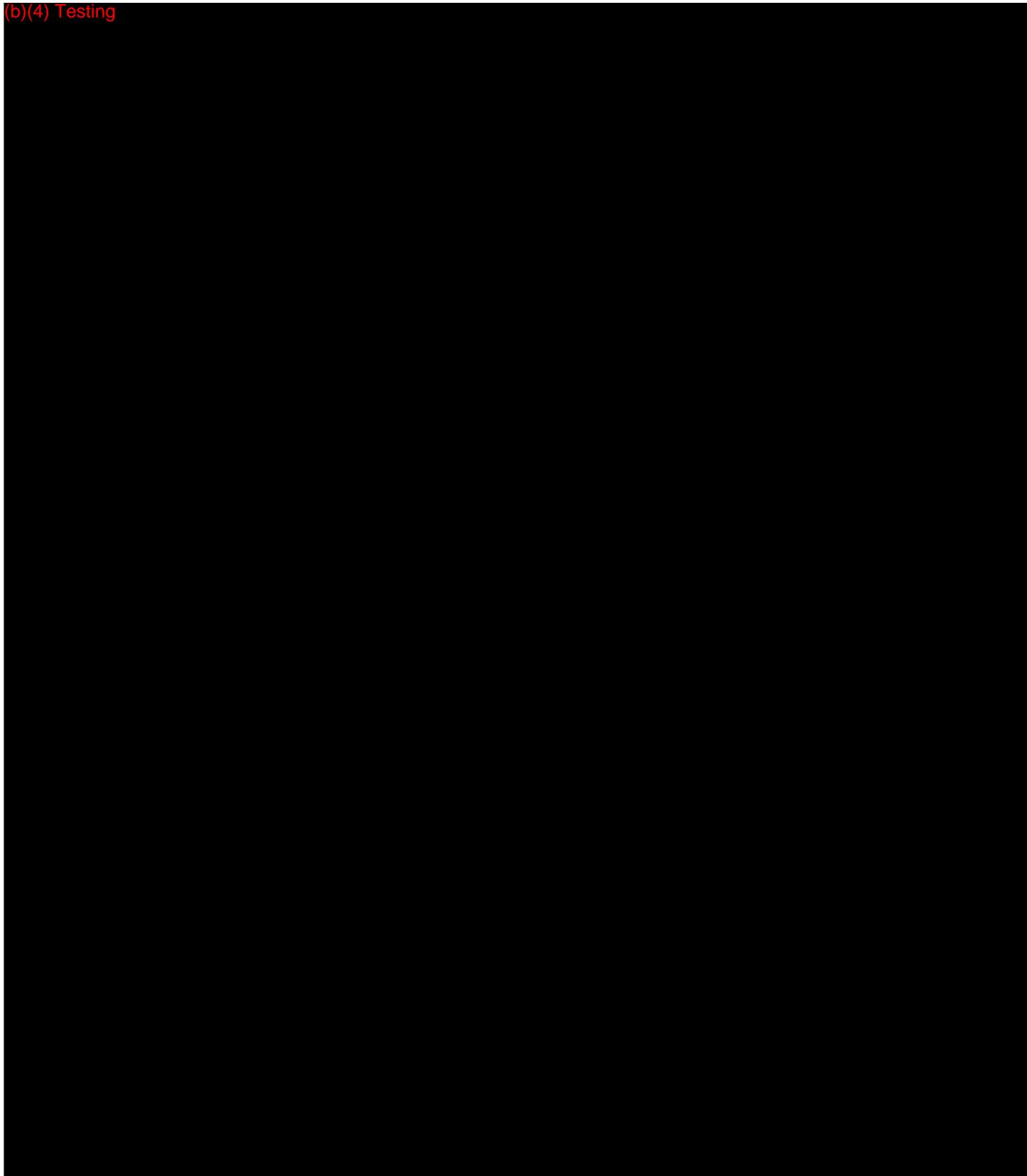
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69

(b)(4) Testing



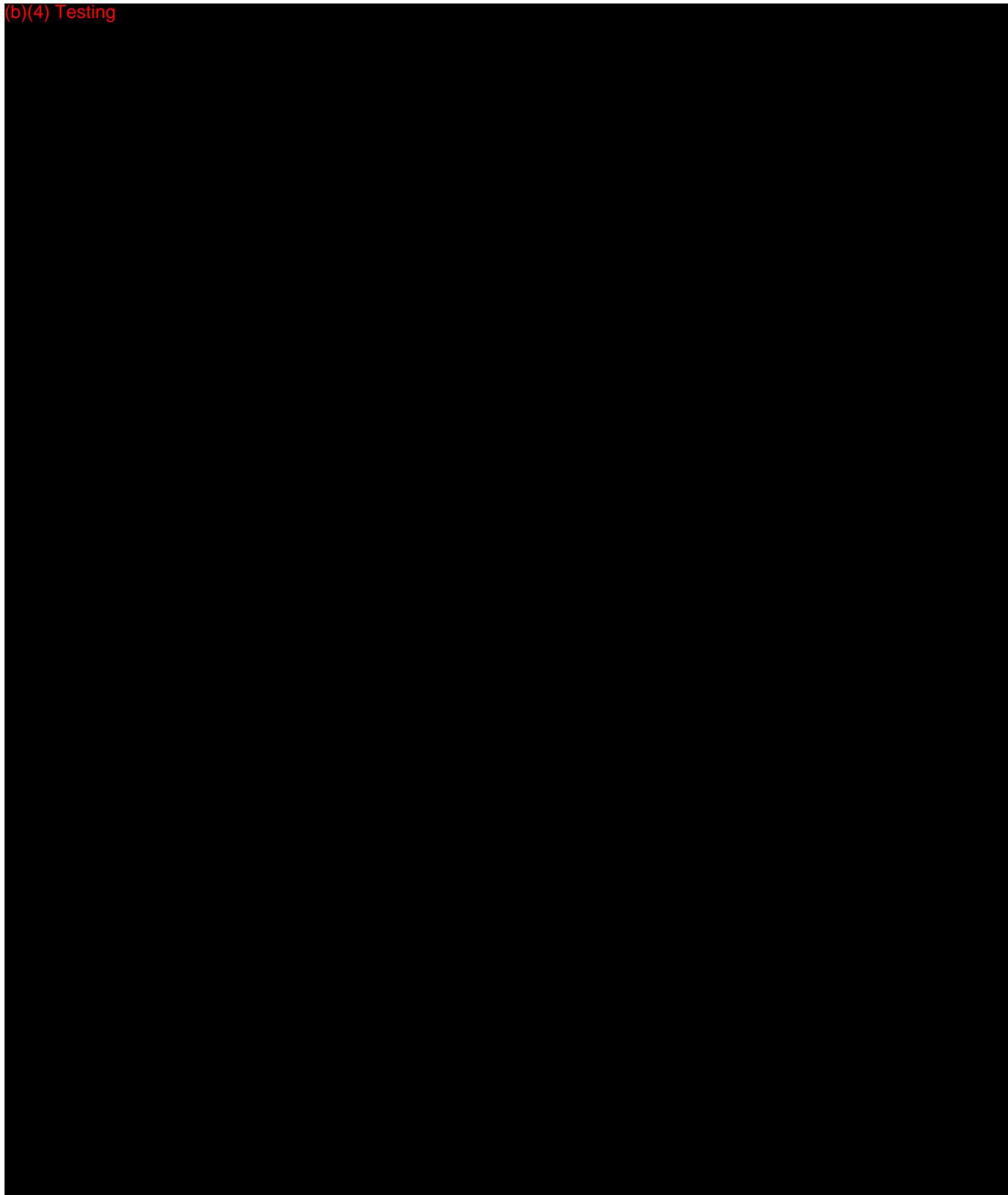
(b)(4) Testing



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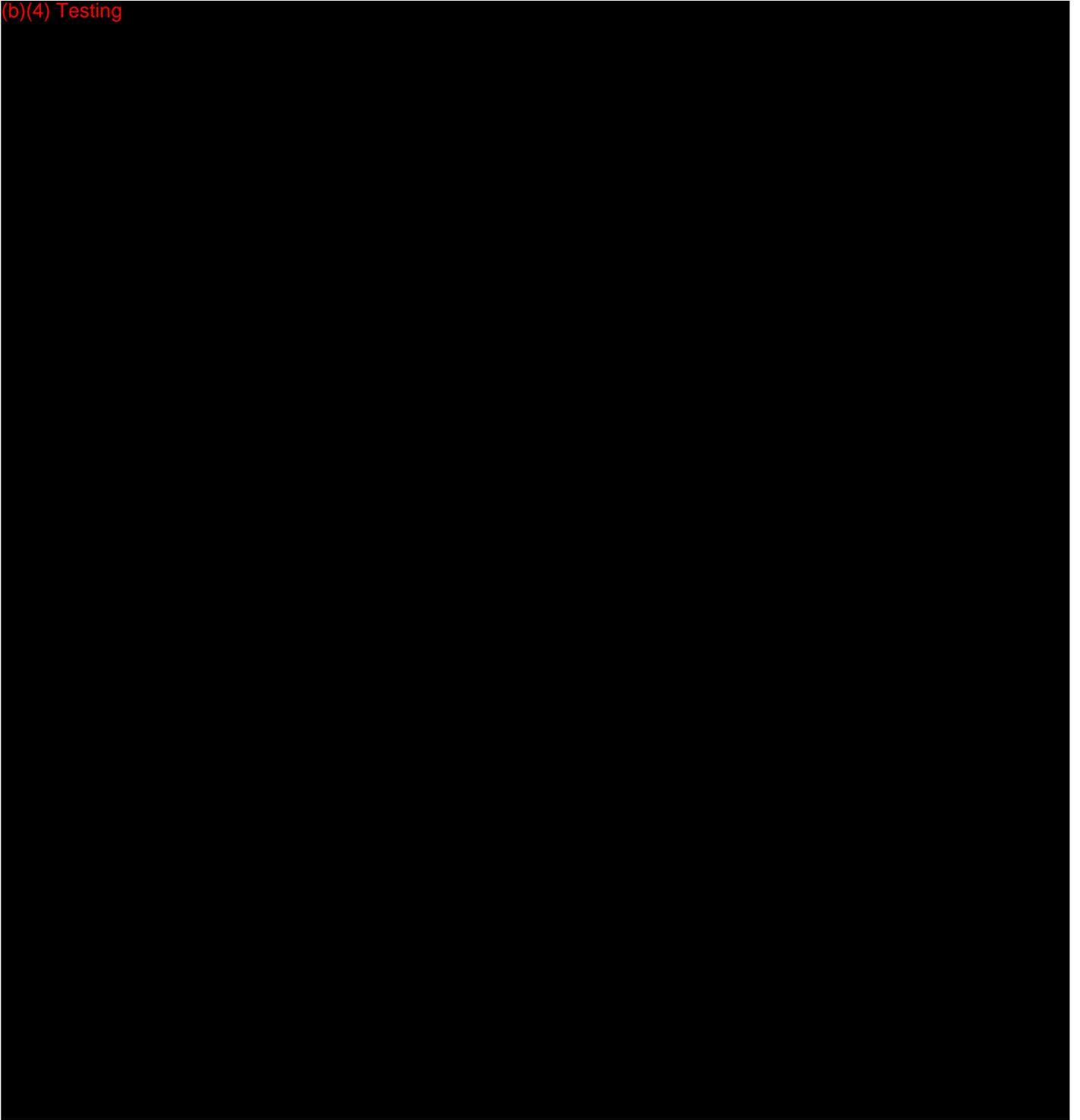
71

(b)(4) Testing



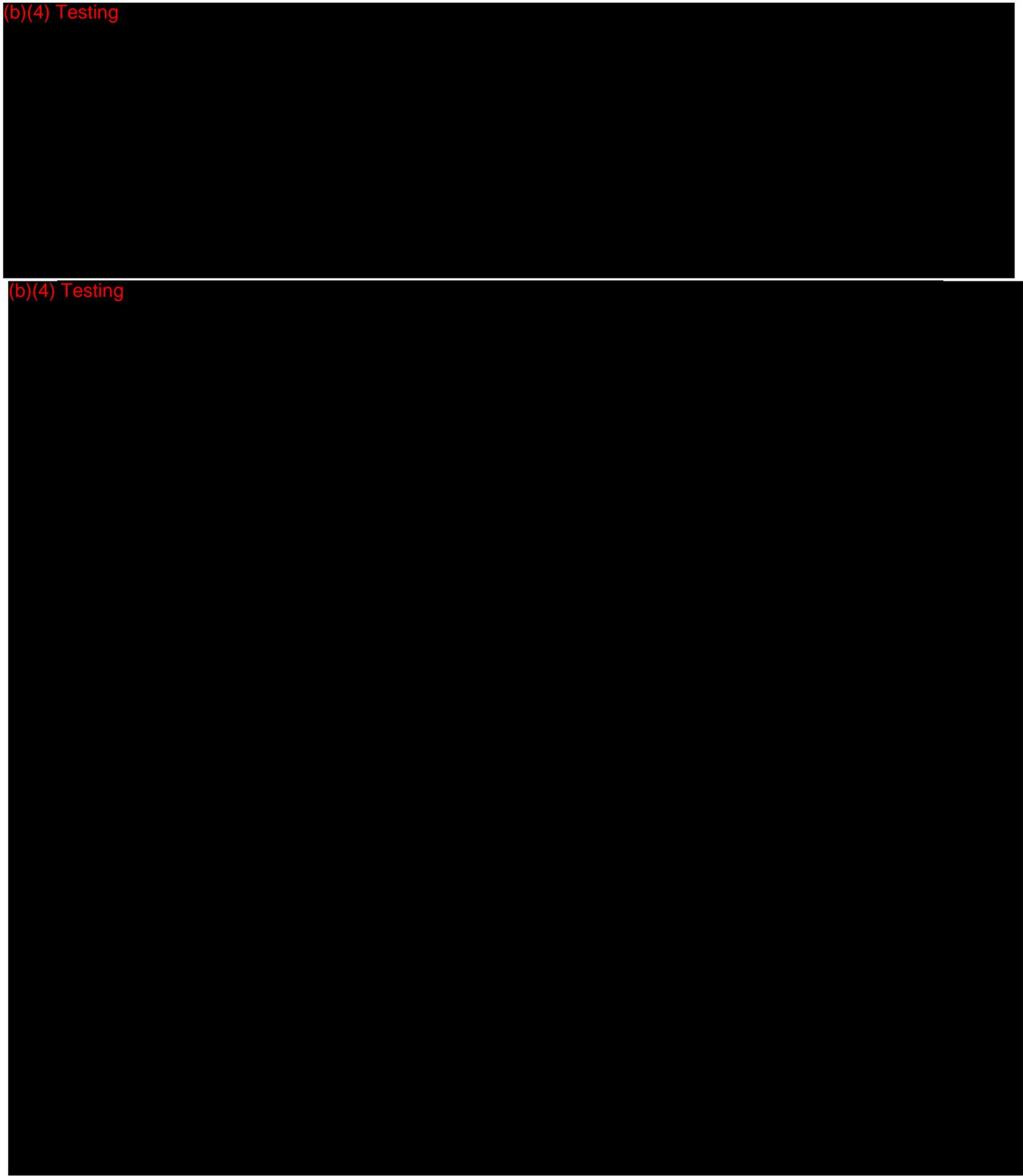
25 October 2013  
Confidential

(b)(4) Testing



### Section 19: Performance Testing - Animal

(b)(4) Testing



(b)(4) Testing

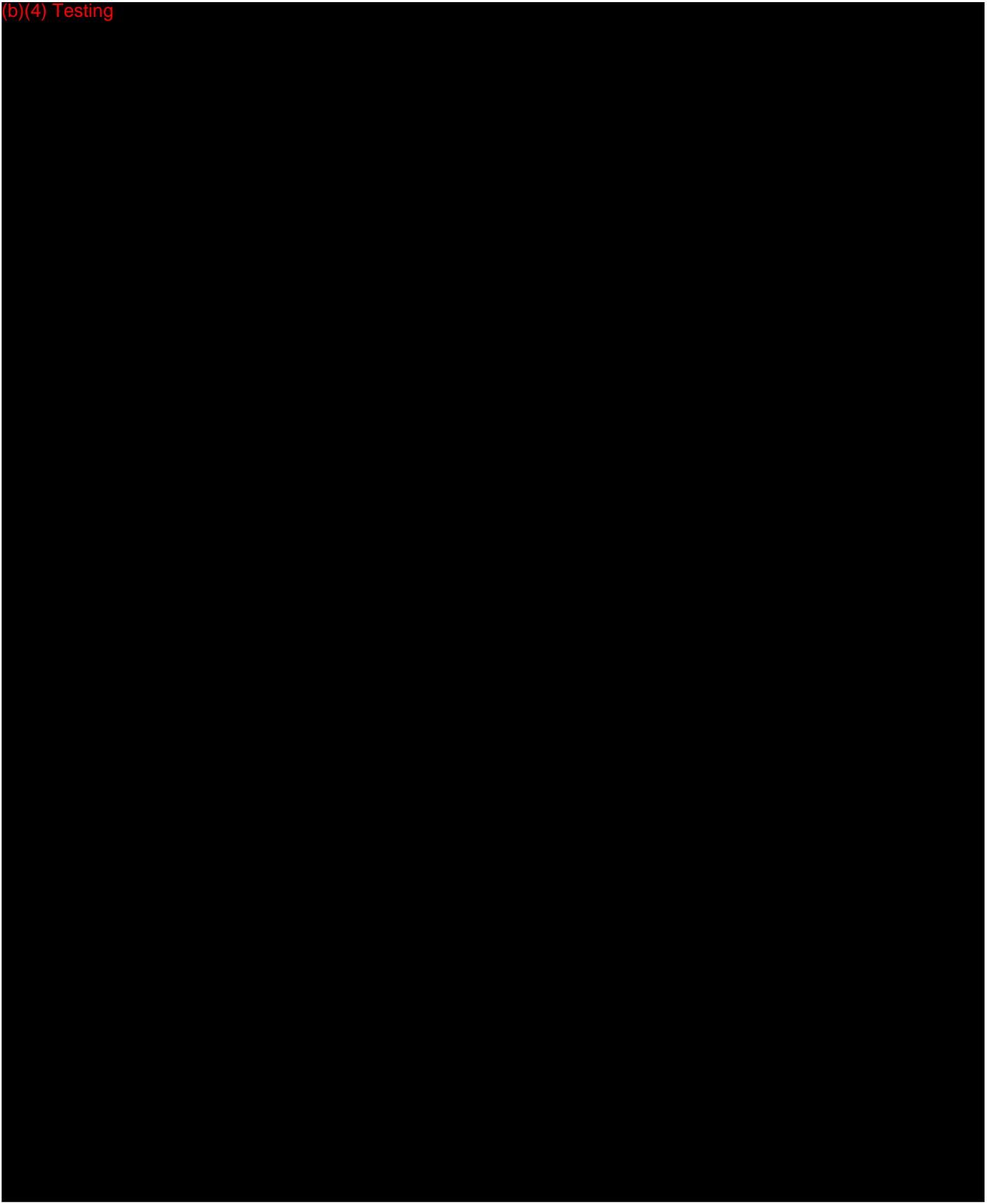
## Study Method

HARMONIC FOCUS Shears + Adaptive Tissue Technology functions via MIN and MAX power level settings. (b)(4) Testing



(b)(4) Testing

(b)(4) Testing

















































## **Section 20: Performance Testing - Clinical**

This section is not applicable. Clinical data is not required to support substantial equivalence. No new issues of safety and effectiveness were raised by the device design.

### **Section 21: 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 c/o Brian Godwin		2. Date of the Application/Submission Which This Certification Accompanies 10/25/2013	
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) 4545 Creek Rd		(Tel): (513) 337-3623	
Address 2 (Apartment, suite, unit, building, floor, etc.)		(Fax): (513) 337-4366	
City Cincinnati	State/Province/Region OH		
Country USA	ZIP or Postal Code 45242		

## 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® Shears + Adaptive Tissue Technology

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

10/25/2013

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:

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Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRAStaff@fda.hhs.gov

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## **Section 22: 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 10993-7:2008, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

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 <sup>1</sup>

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 <sup>2</sup>? .....  Yes       No

FDA Recognition number <sup>3</sup> ..... # 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 <sup>4</sup> 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) <sup>5</sup>? .....  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 <sup>6</sup> 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: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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

<sup>4</sup> 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.

<sup>5</sup> 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>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

**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 <sup>♦</sup>

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 <sup>♦</sup>

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 <sup>♦</sup>

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.

<sup>♦</sup> 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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Rockville, MD 20850

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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 <sup>♦</sup>

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 <sup>♦</sup>

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 <sup>♦</sup>

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?
7	ME EQUIPMENT 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?
8	Protection against electrical HAZARDS from 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?
9	Protection against MECH HAZARDS and ME EQUIPMENT and ME SYS	<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?
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 <sup>♦</sup>

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 <sup>♦</sup>

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 <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

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SUMMARY REPORT TABLE**

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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?
13	HAZARDOUS SITUTATIONS and fault conditions	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
15	Construction of ME EQUIPMENT	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

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.

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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 16	SECTION TITLE 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 <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 17	SECTION TITLE Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------------	---	--

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

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Department of Health and Human Services  
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 (To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

IEC 60601-1-2:2007, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagn

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... #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 <sup>4</sup> 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) <sup>5</sup>? .....    

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 <sup>6</sup> that is associated with this standard?.....       
 If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <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 <sup>♦</sup>

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 <sup>♦</sup>

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 <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

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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 Safety - Collateral Standard: Electromagn

**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 <sup>♦</sup>

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 <sup>♦</sup>

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 <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ANSI/AAMI/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 <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # 14-76

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

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Does this standard include acceptance criteria? .....       
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Does this standard include more than one option or selection of tests? .....       
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If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

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 <sup>6</sup> 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: Ethylene O

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ANSI/AAMI/ISO 10993-7:2008, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals

**CONFORMANCE WITH STANDARD SECTIONS\***

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

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>  
N/A - No definitions

DESCRIPTION  
Scope of ISO-10993-7, EO Residuals

JUSTIFICATION  
EO sterilized product - EO residual allowable levels

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

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>  
N/A

DESCRIPTION  
N/A

JUSTIFICATION  
N/A

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

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>  
N/A

DESCRIPTION  
N/A

JUSTIFICATION  
N/A

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

## STANDARD TITLE

ANSI/AAMI/ISO 10993-7:2008, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals

**CONFORMANCE WITH STANDARD SECTIONS\***

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

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

Limited Exposure Device - Simulated Use Extraction

## DESCRIPTION

Limited Exposure Devices and Simulated Use Extraction Method Used

## JUSTIFICATION

Refer to IFU for devices' intended use; Simulated extraction method use - 24 hours extraction

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

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

Section 5.2 used - Release of products without dissipation curve data

## DESCRIPTION

Simulated use extraction method used to quantify EO and ECH residuals after 24:30 hours heated aeration.

## JUSTIFICATION

Acceptable method for product release is being used based on Section 5.2 of the standard. Devices have demonstrated 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 checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

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 has demonstrated acceptable EO and ECH residual levels per ISO 10993-7.

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

AAMI/ANSI/ISO 10993-1 :2009 Biological evaluation of medical devices - Part I: Eval and testing within a risk mngmt process

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... #2-156

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

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 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> 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

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
AAMI/ANSI/ISO 10993-1 :2009 Biological evaluation of medical devices - Part I: Eval and testing within a risk mngmt 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 <sup>♦</sup>

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 <sup>♦</sup>

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 <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

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STANDARD TITLE  
AAMI/ANSI/ISO 10993-1 :2009 Biological evaluation of medical devices - Part I: Eval and testing within a risk mngmt process

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	General principles applying to biological evaluation of medical deviecs	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

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 <sup>♦</sup>

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 <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

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AAMI/ANSI/ISO 10993-1 :2009 Biological evaluation of medical devices - Part I: Eval and testing within a risk mngmt process

**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 <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED <sup>♦</sup>

DESCRIPTION

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

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

**Barlow, Lenny \***

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**From:** Barlow, Lenny \*  
**Sent:** Wednesday, December 04, 2013 12:53 PM  
**To:** bgodwin@its.jnj.com  
**Cc:** DCCLetters  
**Subject:** k133314 Correspondence  
**Attachments:** k133314.pdf



## COVER SHEET MEMORANDUM

**From:** Reviewer Name Jennifer Stevenson  
**Subject:** 510(k) Number K133314  
**To:** The Record

**Please list CTS decision code:** SE - Substantially Equivalent

- Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)
- Hold (Additional Information or Telephone Hold)
- Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page ( <i>Attach IFU</i> )	X	
510(k) Summary or 510(k) Statement ( <i>Attach Summary or Statement</i> )	X	
Truthful and Accurate Statement ( <i>Must be present for a Final Decision</i> )	X	
Is the device Class III?		X
Does firm reference standards? (If yes, please attach <u>Form 3654</u> .)	X	
Is this a combination product?		X
Is this a reprocessed single use device? (See <u>Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices</u> .)		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		X
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X
Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)		X
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		X

Nanotechnology		×
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		×

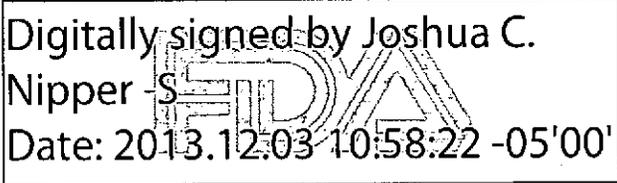
**Regulation Number:** unassigned

**Class:** Unclassified

**Product Code:** LFL

**Additional Product Codes:**

**Digital Signature Concurrence Table**  
 (Not all signatures may be required)

Branch Chief Sign-Off	 <p>Digitally signed by Long H. Chen -A                  DN: c=US, o=U.S. Government,                  ou=HHS, ou=FDA, ou=People,                  cn=Long H. Chen -A,                  0.9.2342.19200300.100.1.1=130036                  9056                  Date: 2013.11.22 14:09:59 -05'00'</p>
Division Sign-Off	 <p>Digitally signed by Joshua C.                  Nipper -S                  Date: 2013.12.03 10:58:22 -05'00'</p>