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K160752

ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

March 17, 2016

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

FDA/CDRH/DCC
MAR 18 2016
RECEIVED

Dear Sir or Madam:

Pursuant to 21 CFR 807.90, Ethicon Endo-Surgery is submitting two copies (one paper copy and one electronic copy) of this 510(k) notification for the Ethicon Endo-Surgery Harmonic HD 1000i Shears. The design of the new device is based upon the predicate device, the Harmonic ACE+ Shears with Advanced Hemostasis cleared under K132612 on 17 October, 2013.

The following information is provided in the 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:	David Locke, DRSc, MS, RAC Senior Regulatory Affairs Specialist Phone: (513) 337-1281 FAX: (513) 337-4366 Email: dlocke1@its.jnj.com
Confidentiality Preference:	Please keep this submission confidential
Classification Regulation:	Unassigned
Device Class:	Class II
Panel:	General & Plastic Surgery
Classification Code:	LFL

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

1

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

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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) **MD6084775** has been assigned to this submission. A copy of the Medical Device User Fee Cover Sheet Form 3601 has been included in Section 1 of the submission.

Per the instructions contained in the guidance *Electronic Copies for Pre-Market Submissions*, an electronic copy of this submission is included which is an exact duplicate of the original paper submission. The electronic copy is accompanied by one paper copy of the 510(k) cover letter and the 510(k) truthful and accuracy statement with original signatures.

Thank you in advance for your consideration of our application. If there are any questions please feel free to contact me at (513) 337-1281 or by email at dlocke1@its.jnj.com. If I am not available, the alternate contact person for this submission is Hortense Allison, Director of Regulatory Affairs, at (513) 337-3592 or hallison@its.jnj.com.

Sincerely,

David M Locke

David M. Locke, DRSc, MS, RAC
Senior Regulatory Affairs Specialist

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510(k) Premarket Notification (Traditional)

Harmonic® HD 1000i Shears

March 17, 2016

Ethicon Endo-Surgery, LLC

475 Calle C

Guaynabo, PR 00969

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

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Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: Date Received by DCC:

Lead Reviewer:

Branch: Division: Center/Office:

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

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X		
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."	X		
Comments:			
3) If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."			X
Comments:			

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4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X		
Comments:			
5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X	
Comments:			
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm If no clinical studies have been submitted, mark "N/A."			X
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
- If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
- If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
- If the answer to 6 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.

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Organizational Elements

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

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	X		13
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
3) All pages of the submission are numbered.	X		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special).	X		1
Comments:			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X				
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name	X				19
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X				19
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format. (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*	X				26
4) Submission contains a 510(k) Summary or 510(k) Statement.	X				28
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format.* *(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*	X				33
6) Submission is a Class III 510(k) device.			X		
7) Submission contains clinical data			X		
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	X				41
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.			X		
B. Device Description					
9) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.			X		
10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	X				42-48
11) The submission includes descriptive information for the device, including the following:					
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	X				42-48
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X				42-48
c) A list and description of each device for which clearance is requested.	X				45

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d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	X				204
12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.			X		
C. Substantial Equivalence Discussion					
13) Submitter has identified a predicate device(s), including the following information:					
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*	X				49
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	X				
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
a) Indications for Use	X				51-54
b) Technology, including features, materials, and principles of operation	X				51-54
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
15) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	X				55-93
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X				63
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X				63-67
16) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X				78

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17) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements").	X				58
18) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device.			X		
19) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X		
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that the device, and/or accessories, and/or components are: (one of the below must be checked)					94
X Provided sterile, intended to be single-use					
Requires processing during its use-life					
Non-sterile when used (and no processing required)					
Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
Sterility status not needed for this device (e.g., software-only device)					
Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.*					
20) Assessment of the need for cleaning and subsequent disinfection or sterilization information					
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X				94
b) Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected.			X		
c) Identification of device, and/or accessories, and/or components that are reusable.			X		
21) If the device, and/or accessory, and/or a component is provided sterile:					
a) Sterilization method is stated for each component (including dose for radiation sterilization).	X				94
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).	X				94-96
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	X				95
d) Sterility Assurance Level (SAL) is stated.	X				94

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
e) Submission includes description of packaging.	X				98-99
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).			X		
22) If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected:			X		
23) The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.			X		
F. Shelf Life					
24) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	X				96
25) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	X				98-99
26) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	X				96-98
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that there: (one of the below must be checked)					100
X Are direct or indirect patient-contacting components.					
Are no direct or indirect patient-contacting components.					
Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
Patient contact information not needed for this device (e.g., software-only device)					
Patient contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
27) Submission includes a list identifying each of patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	X				100
28) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter)	X				100

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29) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X				100
H. Software					
Submission states that the device: (one of the below must be checked)					101
	Does contain software/firmware				
X	Does not contain software/firmware				
	Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)				
	Software/firmware information not needed for this device (e.g., surgical suture, condom)				
	Software/firmware information is needed or need unclear				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
I. Electrical Safety and EMC					
Electrical Safety Submission states that the device: (one of the below must be checked)					102
X	Does require electrical safety evaluation				
	Does not require electrical safety evaluation				
	Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)				
	Electrical safety information not needed for this device (e.g., surgical suture, condom)				
	Electrical safety information is needed or need unclear				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
32) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard), **OR** Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	X				102
EMC Submission states that the device: (one of the below must be checked)					102
X	Does require EMC evaluation				

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Does not require EMC evaluation					
Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
EMC information not needed for this device (e.g., surgical suture, condom)					
EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
33) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) **OR** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	X				102
J. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.					
34) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions.	X				205
a) Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	X				53-54
35) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding performance data that is applicable to the subject device.			X		
36) If literature is referenced in the submission, submission includes:			X		
37) For each completed animal study, the submission provides the following:					
a) Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120.	X				300
b) Submission includes final study report which includes all elements outlined in 21 CFR 58.185.	X				317
c) Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	X				205
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)					

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	is an in vitro diagnostic device.					
X	is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.						

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Decision: ◯ Accept ◯ Refuse to Accept

If Accept, notify applicant.

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

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

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

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

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

The Medical Device User Fee Cover Sheet is found on the following page.

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

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

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

PAYMENT IDENTIFICATION NUMBER: (b) (4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

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

ETHICON ENDO SURGERY INC
4545 CREEK ROAD
CINCINNATI
OH 45242
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****7572

2. CONTACT NAME
David Locke
2.1 E-MAIL ADDRESS
dlocke1@its.jnj.com
2.2 TELEPHONE NUMBER (include Area code)
513-337-1281
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] 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?
[X] 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.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b) (4)
28-Oct-2015

Form FDA 3601 (05/13)

"Close Window" Print Cover sheet

https://userfees.fda.gov/OA_HTML/mdufmaCSedCfgItemsPopup.jsp?vname=David%2... 10/28/2015 Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

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

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

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
March 17, 2016	(b) (4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

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	Establishment Registration Number *(if known)*		
Ethicon Endo-Surgery, LLC	3005075853		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
N/A	(787) 653-4603		
Street Address	**FAX Number *(including area code)***		
475 Calle C	(787) 653-4631		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Guaynabo	Puerto Rico	00969	USA
Contact Name			
Marjorie Medina			
Contact Title	**Contact E-mail Address**		
Director, Plant Quality	mmedina6@its.jnj.com		

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

Company / Institution Name			
Ethicon Endo-Surgery, LLC			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
N/A	(513) 337-1281		
Street Address	**FAX Number *(including area code)***		
4545 Creek Road	(513) 337-4366		
City	**State / Province**	**ZIP Code**	**Country**
Cincinnati	Ohio	45242	USA
Contact Name			
David Locke			
Contact Title	**Contact E-mail Address**		
Senior Regulatory Affairs Specialist	dlocke1@its.jnj.com		

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

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

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify):*

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LFL	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K132612	1	HARMONIC ACE®+ Shears with Advanced Hemostasis	1	Ethicon Endo-Surgery, LLC
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

	Trade or Proprietary or Model Name for This Device		Model Number
1	HARMONIC® HD 1000i Shears 20 cm Length	1	HARHD20
2	HARMONIC® HD 1000i Shears 36 cm Length	2	HARHD36
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	C.F.R. Section *(if applicable)*	Device Class
LFL	Unassigned	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Indications *(from labeling)*

The HARMONIC HD 1000i Shears instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, energy-aided dissection, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7□mm in diameter, using the Energy button with Advanced Hemostasis.

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

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

(b) (4)

(b) (4)

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

SECTION I UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601-1	IEC	IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	2005	12/1/2005
2	60601-1-2	IEC	IEC 60601-1-2:2007, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility	2007	3/1/2007
3	EN ISO 11135-1:2014	EN ISO	11135:2014, Medical Devices - Validation & Routine Control of Ethylene Oxide Sterilization	2014	7/15/2014
4	AAMI ANSI ISO 10993-7:2008	AAMI ANSI ISO	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals	2008	01/01/2008
5					
6					
7					

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

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

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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

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Section 3: Cover Letter

The 510(k) cover letter for the device is provided on the following pages.

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

March 17, 2016

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

Dear Sir or Madam:

Pursuant to 21 CFR 807.90, Ethicon Endo-Surgery is submitting two copies (one paper copy and one electronic copy) of this 510(k) notification for the Ethicon Endo-Surgery Harmonic HD 1000i Shears. The design of the new device is based upon the predicate device, the Harmonic ACE+ Shears with Advanced Hemostasis cleared under K132612 on 17 October, 2013.

The following information is provided in the 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:	David Locke, DRSc, MS, RAC Senior Regulatory Affairs Specialist Phone: (513) 337-1281 FAX: (513) 337-4366 Email: dlocke1@its.jnj.com
Confidentiality Preference:	Please keep this submission confidential
Classification Regulation:	Unassigned
Device Class:	Class II
Panel:	General & Plastic Surgery
Classification Code:	LFL

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

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

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) (b) (4) has been assigned to this submission. A copy of the Medical Device User Fee Cover Sheet Form 3601 has been included in Section 1 of the submission.

Per the instructions contained in the guidance *Electronic Copies for Pre-Market Submissions*, an electronic copy of this submission is included which is an exact duplicate of the original paper submission. The electronic copy is accompanied by one paper copy of the 510(k) cover letter and the 510(k) truthful and accuracy statement with original signatures.

Thank you in advance for your consideration of our application. If there are any questions please feel free to contact me at (513) 337-1281 or by email at dlocke1@its.jnj.com. If I am not available, the alternate contact person for this submission is Hortense Allison, Director of Regulatory Affairs, at (513) 337-3592 or hallison@its.jnj.com.

Sincerely,

David M. Locke

David M. Locke, DRSc, MS, RAC
Senior Regulatory Affairs Specialist

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

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

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

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Harmonic HD 1000i Shears

Indications for Use *(Describe)*
Indications

The Harmonic HD 1000i Shears instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, energy-aided dissection, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

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

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

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

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Section 5: 510(k) Summary

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

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

510(k) Summary

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

Contact David Locke, DRSc, MS, RAC
Senior Regulatory Affairs Specialist
Ethicon Endo-Surgery, Inc.
Telephone: (513) 337-1281
Email: dlocke1@its.jnj.com

Date Prepared

March 17, 2016

Device Name

Trade Name: Harmonic® HD 1000i Shears

Common Name: Instrument, Ultrasonic Surgical

Classification Name

Instrument, Ultrasonic Surgical (Unassigned, Product Code: LFL)

Regulatory Class

Class II

Predicate Device

HARMONIC ACE®+ Shears with Advanced Hemostasis, cleared under K132612 on October 17th, 2013

Device Description

The HARMONIC HD 1000i Shears are a sterile, single patient use device used for dissection, grasping, coagulation, and cutting between the blade and clamp arm. It consists of an ergonomic grip housing assembly with two hand control buttons: 1) Energy button for power levels 1-5 and, 2) Energy with Advanced Hemostasis button for large vessel sealing. The device is available in two shaft lengths, 20 cm and 36 cm, and both device shafts can be rotated continuously to facilitate visualization and access to targeted tissue.

An integrated audible and tactile mechanism in the grip housing indicates full trigger closure. The device has a clamp arm and coated curved blade that is designed to work through a 5 mm trocar, through a 5 mm reducer cap in a larger diameter trocar, or through an incision without the

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

use of a trocar. The blade used in the HARMONIC HD 1000i Shears has a slightly different blade design than that of the predicate device, the HARMONIC ACE+ Shears with Advanced Hemostasis (cleared under K132612 on October 17, 2013), and is also slightly longer and more tapered than the predicate device. Additionally, two dashes have been added to the device which are intended to represent relative vessel size.

The distal/front Energy button is indicated for vessels up to 5 mm in diameter. The Energy with Advanced Hemostasis button (the Green button), which is found on the side of the device handle, is designed for larger vessels and is indicated for vessels up to 7 mm in diameter. The device utilizes Adaptive Tissue Technology (the technological characteristics of which were first cleared under K120729 on May 17, 2012). This technology provides the generator with the ability to identify and monitor the instrument during use.

The HARMONIC HD 1000i Shears are designed for use exclusively with the Ethicon Generator 11 (GEN11).

Indications for Use

The Harmonic HD 1000i Shears instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, energy-aided dissection, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis.

Technological Characteristics

The Ethicon Endo-Surgery HARMONIC HD 1000i Shears incorporate the same technological characteristics as that of the ultrasonic predicate device, HARMONIC ACE+ Shears with Advanced Hemostasis. Both the subject and predicate devices 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 HD 1000i Shears. Further, both devices have an ergonomic grip housing assembly which allows for manual closure of the jaw and the devices contain buttons which allow for the manual application of energy. To as where the predicate HARMONIC ACE+ Shears with Advanced Hemostasis contains three buttons allowing for manual energy activation, the subject HARMONIC HD 1000i Shear only contains two buttons, allowing for manual energy activation.

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Performance Data

(b) (4) Test Data

[redacted]

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

(b) (4) Test Data



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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Section 6: Truthful and Accuracy Statement

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

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

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 Specialist for Ethicon Endo-Surgery Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

David M. Locke, DRSc, MS, RAC
Senior Regulatory Affairs Specialist
Ethicon Endo-Surgery, Inc.

15 MARCH 2016

Date

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Section 7: Class III Summary and Certification

This section does not apply, as the HARMONIC® HD 1000i Shears are Class II devices.

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Section 8: Financial Certification or Disclosure Statement

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

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Section 9: Declaration of Conformity and Summary Reports

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

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

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® HD 1000i Shears (models HARHD20 and HARHD36). As part of this submission, data has been provided to support substantial equivalence between the subject device mentioned above and the previously cleared HARMONIC ACE®+ Shears with Advanced Hemostasis device (K132612).

Device Name

Trade Name: HARMONIC® HD 1000i Shears

Common Name: Instrument, Ultrasonic Surgical

Classification Name

Instrument, Ultrasonic Surgical (Unassigned, Product Code LFL)

Regulatory Class

Class II

Predicate Device

HARMONIC ACE®+ Shears with Advanced Hemostasis, cleared under K132612 on October 17, 2013

Device Description

The HARMONIC HD® 1000i Shears are sterile, single patient use device used for dissection, grasping, coagulation, and cutting between the blade and clamp arm (see Figure 10-1). It consists of an ergonomic grip housing assembly with two hand control buttons: 1) Energy button for power levels 1-5 and, 2) Energy with Advanced Hemostasis button for large vessel sealing. The device is available in two shaft lengths, 20 cm and 36 cm, and both device shafts can be rotated continuously to facilitate visualization and access to targeted tissue.

(b) (4)

(b) (4)

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

(b) (4)

The HARMONIC HD 1000i Shears are designed for use exclusively with the Ethicon Generator 11 (GEN11).

(b) (4) Proprietary Information

Figure 10-2: Clamp Arm and Coated Blade

Figure 10-3: Integrated Transducer

(b) (4) Proprietary Information

Tables 10-1 through 10-3 below contains comparisons between the subject and predicate device with respect to indications and contraindications, technology and performance specifications and patient contacting materials, respectively; see Appendix B for a device Assembly drawing of the subject device.

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

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

Indications for Use	
HARMONIC HD 1000i *(subject device)*	**HARMONIC ACE®+ Shears with Advanced Hemostasis** *(predicate device)*
The Harmonic HD 1000i Shears instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, ***energy-aided dissection****, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis.*	*The Harmonic ACE® + Shears with Advanced Hemostasis are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, laser and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7mm in diameter using the Advanced Hemostasis hand control button.*
Contraindications	
HARMONIC HD 1000i *(subject device)*	**HARMONIC ACE®+ Shears with Advanced Hemostasis** *(predicate device)*
• *The instruments are not indicated for incising bone.* • *The instruments are not intended for contraceptive tubal occlusion.*	Same

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

(b) (4) Proprietary Information

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Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Device Instructions for Use

1 Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.

2 Connect the instrument to the generator and turn the generator power on.

3 Select the desired power level using the INCREASE and DECREASE buttons on the generator touchscreen. Only the power level for the Energy button can be adjusted (1-5). The system defaults to power level 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.

4 Close the clamp arm by closing the trigger, and insert the shaft through a trocar or incision.

5 Position the tissue within the jaws at the desired location. The instrument's shaft can be rotated continuously using the rotation knob to facilitate visualization and access to target tissue.

6 Squeeze the trigger until it stops against the plastic handle (and a click is heard) to clamp targeted tissue between the jaws. To achieve complete sealing, the trigger should be fully closed and the vessel fully contained between clamp arm and blade of device. An audible and tactile "click" indicates full trigger closure. To achieve full closure of the jaws of the device, squeeze the plastic trigger until you feel it stop against the plastic handle (plastic to plastic). Grip force needs to be maintained throughout the transection to keep trigger closed.

7 To activate the instrument blade, press one of the foot pedal switches or one of the energy buttons on the instrument. Pressing the left foot pedal of the footswitch or the Energy button with Advanced Hemostasis on the instrument activates Advanced Hemostasis. When using the Energy button with Advanced Hemostasis, energy is not delivered unless the jaws are completely closed. This button activates an algorithm in the generator that, in conjunction with full trigger closure, allows for sealing larger vessels (up to 7 mm in diameter). Pressing the right foot pedal of the footswitch or Energy button on the instrument activates the selected power level (1-5). The Energy button allows for sealing vessels up to 5 mm in diameter with full trigger closure and can enable other soft tissue applications (backcutting, scoring, drilling/otomy creation, etc.), where full trigger closure is not needed (see Table 11-5). The generator emits one of the audible tones listed in the table below to indicate when the instrument blade is first activated (see Table 11-6). The generator changes to a second audible 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 audible tone change is not a substitute for surgical experience (see Table 11-7).

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

8 Close the clamp arm by closing the trigger and remove the shaft from the trocar or incision.

9 Unplug the instrument from the generator.

10 Turn the generator OFF at the power switch.

11 Dispose of the instrument and cable in an appropriate container. No disassembly is required.

(b) (4)

(b) (4)

(b) (4)

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Section 12: Substantial Equivalence Discussion

Ethicon Endo-Surgery HARMONIC® HD 1000i Shears are compared to the following predicate devices:

- HARMONIC ACE®+ Shears with Advanced Hemostasis, cleared under K132612 on October 17, 2013

The 510(k) Decision-Making Flowchart from the FDA Guidance for Industry and Food and Drug Administration Staff titled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" from 2014 was used in determining substantial equivalence of the Subject 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.

Decision 1
Is the predicate device legally marketed?

Yes.

Predicate Device: HARMONIC ACE®+ Shears with Advanced Hemostasis, cleared under K132612 on 17 October 2013

Subject Device: HARMONIC HD 1000i Shears

Decision 2
Do the devices have the same intended use?

(b) (4)

[redacted]

Decision 3
Do the devices have the same technological characteristics?

Yes.

The subject HARMONIC® HD 1000i Shears device and predicate HARMONIC ACE®+ Shears with Advanced Hemostasis device use the same harmonic technology to perform their intended use.

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

(b) (4) Proprietary Information

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Tables 12-1 through 12-3 contain comparisons between the subject and predicate devices with respect to indications/contraindications, technology and performance specifications, and patient contacting materials, respectively.

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

Indications for Use	
HARMONIC HD 1000i *(subject device)*	**HARMONIC ACE®+ Shears with Advanced Hemostasis** *(predicate device)*
*The Harmonic HD 1000i Shears instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, ***energy-aided dissection**, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis.*	*The Harmonic ACE® + Shears with Advanced Hemostasis are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, laser and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7mm in diameter using the Advanced Hemostasis hand control button.*
Contraindications	
HARMONIC HD 1000i *(subject device)*	**HARMONIC ACE®+ Shears with Advanced Hemostasis** *(predicate device)*
• *The instruments are not indicated for incising bone.* • *The instruments are not intended for contraceptive tubal occlusion.*	Same

*****Energy-aided dissection was added to the indication and is supported with preclinical dissection data found in Section 19, Performance Testing – Animal.

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

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Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

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.

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Form Approved: OMB No. 0910-0616. Expiration Date: 2/28/2018. See PRA Statement on page 2.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

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

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

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
Ethicon Endo-Surgery, LLC

2. Date of the Application/Submission Which This Certification Accompanies
03/17/2016

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
475 Calle L

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City
Gauynabo

State/Province/Region
PR

Country
USA

ZIP or Postal Code
00969

4. Telephone and Fax Numbers *(Include country code if applicable and area code)*

(Tel): (787) 277-6654

(Fax): (787) 277-0042

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)

Common Name: Harmonic HD 1000i Shears
Catalog Number: HARHD20, HARHD36

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

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

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	Title
David Locke	Senior Regulatory Affairs Specialist

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) 337-1281

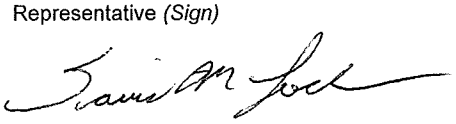
(Fax): (513) 337-4366

14. Date of Certification

03/15/2016

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

Sign



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

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

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

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

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

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Section 22: Form FDA 3654

This section contains completed copies of FDA Form 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 5-54)

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

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

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

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

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	#N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

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

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

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	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Normative references	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terminology and definitions	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

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	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	General requirements for testing ME equiptment	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Classification of ME equipment and ME systems	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	ME equipment identifications, marking and documents	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Protection against electrical hazards from ME equipment	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9	Protection against mechanical hazards and ME equipment and ME systems	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

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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	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
11	Protection against excessive temperatures and other hazards	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
12	Accuracy of controls and instruments and protection against hazardous output	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
13	Hazardous situations and fault conditions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
14	Programmable electrical medical systems (PEMS)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
15	Construction of ME equipment	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
16	ME systems	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
17	Electromagnetic compatibility of ME equipment and ME systems	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

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

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-53	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope, object, and related standards	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Normative references	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terminology and definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

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CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	General requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Identification, marking, and documents	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Electromagnetic compatibility	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

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

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-452	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Use of International Std ISO-11135-1:2014 - Sterilization of Health Care Products - Ethylene Oxide

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

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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Normative references	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terms and Definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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SUMMARY REPORT TABLE

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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Quality Management Systems	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Sterilizing Agent Characterization	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Process and Equipment Characterization	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Product Definition	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Process Definition	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9	Validation	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10	Routine Control and Monitoring	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
11	Product Release from Sterilization	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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SUMMARY REPORT TABLE

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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
12	Maintaining Process Effectiveness	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

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

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-278	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

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

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

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

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

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A, no deviations

DESCRIPTION
Scope of ISO-10993-8, EO Residuals

JUSTIFICATION
EO Sterilized Product - EO residual allowable levels

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Normative references	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terminology and definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

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

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

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

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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Requirements	☒ Yes ☐ No ☐ N/A

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

DESCRIPTION
Limited exposure devices and simulated use extraction method used

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

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Product release	☒ Yes ☐ No ☐ N/A

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

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

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

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5.3	Procedure for product release using residue dissipation curves	☐ Yes ☐ No ☒ N/A

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

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

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

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

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Generator G11 (GEN11)

Operator's Manual
Manuel d'utilisation
Bedienungsanleitung
Manuale dell'operatore
Manual do operador
Manual del usuario
Gebruiksaanwijzing
Brugsanvisning
Käyttäjän käsikirja
Εγχειρίδιο χρήσης
Användarmanual
Instrukcja obsługi
Kezelői útmutató
Návod k obsluze
Príručka pre obsluhu
Brukerhåndbok
Kullanım Kılavuzu
Руководство пользователя
Manualul operatorului
操作手册



Ethicon
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English

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English

Overview

Please read all information carefully.

Failure to properly follow the instructions may lead to serious surgical consequences. This manual contains important information for operation of GEN11. It should be kept where it may be referenced during usage, especially for screen translations. Print or copy pages as necessary to keep nearby.

Important: This manual is designed to provide instructions for use of the Generator G11. It is not a reference to surgical techniques. Go to *www.e-ifu.com* for the latest version of this manual.

HARMONIC® and ENSEAL® are trademarks of Ethicon Endo-Surgery.

Standard Conventions Used

The Use of Caution, Warning, and Note Statements

Information relative to the completion of a task in a safe and thorough manner will be supplied in the form of a Caution, a Warning, or a Note statement. These statements are found throughout the documentation.

These statements should be read before continuing to the next step in a procedure.

Warning: A Warning statement indicates an operating or maintenance procedure, practice, or condition that, if not strictly observed, could result in personal injury or loss of life.

Caution: A Caution statement indicates an operating or maintenance procedure, practice, or condition that, if not strictly observed, could result in damage to or destruction of the equipment.

Note: A Note statement indicates an operating or maintenance problem, practice, or condition that is necessary to accomplish a task efficiently.

Chapter 1 - General Information

Indications

The Generator G11 provides radiofrequency power to drive ENSEAL electrosurgical instruments that are used during open or laparoscopic general and gynecological surgery to cut and seal vessels and to cut, grasp, and dissect tissues. In addition, the generator provides power to drive HARMONIC ultrasonic surgical instruments that are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired.

ENSEAL and HARMONIC instruments when used with the Generator G11 have not been shown to be effective for sterilization procedures or tubal coagulation. Do not use these instruments for these procedures.

Contraindications

- The use of the Generator G11 and the attached instruments are contraindicated, when in the judgment of the physician, radiofrequency or ultrasonic surgery would be contrary to the best interest of the patient.
- The instruments are not indicated for incising bone.

Device Description

The Generator G11 supplies energy to the HARMONIC and ENSEAL surgical instruments. The generator uses a touchscreen display interface and has a unique receptacle port that accepts either a HARMONIC or an ENSEAL device. Connectors (HGA11 for HARMONIC and EGA11 for ENSEAL) are used to enable the generator to power legacy devices.

How Supplied

The Generator G11 is supplied in a semi-ready-to-use state. The shipping box contains the Generator G11, power cord and user manual. The disposable Ethicon Endo-Surgery ENSEAL or HARMONIC instruments are not included in this packaging and must be purchased separately. The HARMONIC device connector (HGA11), ENSEAL device connector (EGA11), footswitch (FSW11) and cart (CRT11) are also available separately.

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Illustration and Nomenclature

Front Panel of the Generator

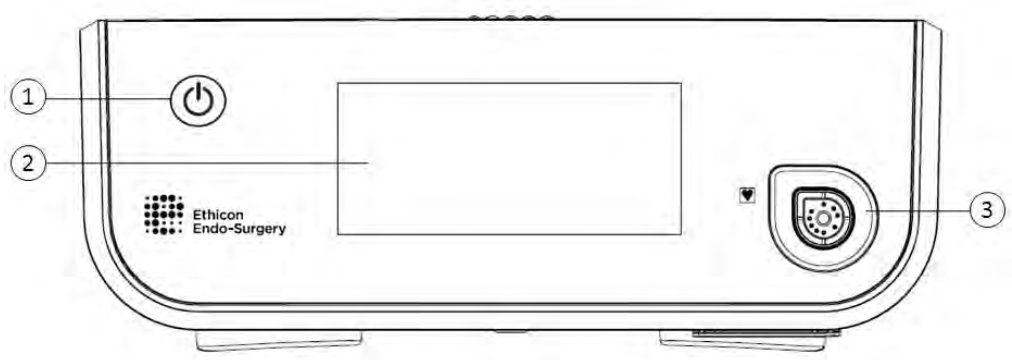


Figure 1

1	POWER ON/OFF SWITCH	Glows green when the generator is powered up.
2	DISPLAY/TOUCH SCREEN	Displays system information and serves as interface for adjusting controls and settings.
3	CONNECTOR/ DEVICE RECEPTACLE	Receptacle used to attach the connectors or devices to the generator.

Back Panel of the Generator



Figure 2

4	POWER CORD RECEPTACLE	Receptacle used to attach the power cord to the generator.
5	FOOTSWITCH RECEPTACLE	Receptacle used to connect the footswitch to the generator.
6	POTENTIAL EQUALIZATION TERMINAL	Provides means for connection to a potential equalization conductor.

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Footswitch

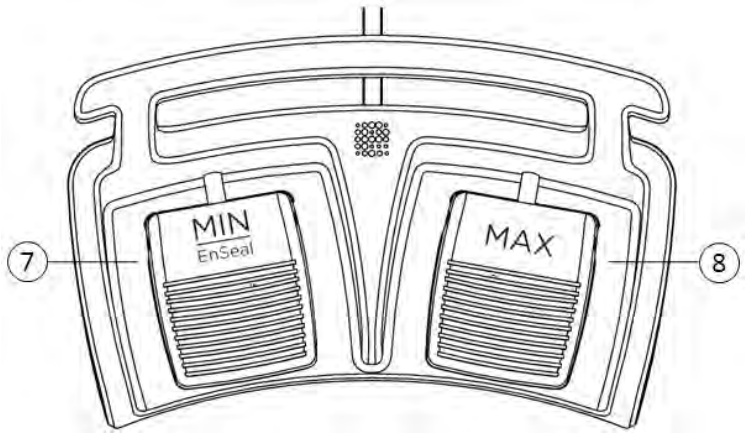


Figure 3

7	MIN (LEFT PEDAL)	Activates power for ENSEAL or minimum power for HARMONIC.
8	MAX (RIGHT PEDAL)	Activates maximum power for HARMONIC.

General Warnings

- Verify that the unit is fully operational prior to administering power output for tissue sealing.
- This equipment is for use only by qualified medical personnel trained in the use of ultrasonic surgery or electrosurgery. Inappropriate use of the equipment by untrained medical personnel may result in hazardous electrical output.
- Do not use in the presence of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen as explosion may occur.
- Non-flammable agents should be used for cleaning and disinfection wherever possible. Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of HF surgery. There is a risk of pooling of flammable solutions under the patient in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be mopped up before the electrosurgery. Attention should be called to the danger of ignition of endogenous or other flammable gases. Some materials, for example cotton and gauze, when saturated with oxygen may be ignited by sparks produced in normal use during electrosurgery.
- Do not operate the Generator G11 in a moist environment as a shock hazard may exist. If liquids have entered the Generator G11 the unit must be returned to the manufacturer for testing prior to use.
- Do not operate the unit in close proximity to volatile solvents such as methanol or alcohol as explosion may occur.
- Avoid use of Generator G11 adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, monitor the Generator G11 and the other equipment to assure normal operation.
- Interference produced by the operation of high-frequency surgical equipment may adversely affect the operation of other electronic medical equipment such as monitors and imaging systems.
- Check if the patient has a pacemaker or implanted cardioverter/defibrillator. Consult the pacemaker or implanted cardioverter/defibrillator manufacturer for information about the effects of radiofrequency energy on these devices.
- Use of accessories and cables other than those specified may result in unpredictable performance, increased electromagnetic emissions, or decreased electromagnetic immunity. No customer modification of this equipment is allowed; modification of this equipment could have a negative impact on electrical safety and electromagnetic emissions.
- No internal user serviceable parts. For service, return the generator to an authorized Ethicon Endo-Surgery service facility.
- To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- To isolate the Generator G11 from supply mains power, disconnect the power cord either from the back panel of the generator or from the wall. Ensure access to these points are kept clear.
- This device is not MR safe and is not MR compatible.
- This device seals vessels up to a maximum diameter of 7 mm depending on the instrument used. Refer to the instrument IFU for further information.

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- As with all energy sources (Electrosurgery, Lasers, 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.
- In case of system failure, ensure availability of the appropriate backup equipment relevant to the specific procedure.
- After removing the instrument, examine the tissue for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.

General Cautions

- The touch screen display of the generator is very sensitive. Do not use sharp metal objects on the touch screen.
- Removing bottom screws or opening of this device invalidates the warranty and could create hazardous condition.
- Read instructions prior to use and follow the hospital's clinical practice guidelines for ultrasonic surgery, electrosurgery, gynecology and laparoscopic procedures.
- Replace fuses only with the appropriate type and rating. See *System Specifications*.
- Do not sterilize the Generator G11. Sterilization will damage the unit.
- Do not restrict the openings on the bottom and the back panel of the Generator G11, as they provide the required airflow for cooling.
- If electromagnetic interference with other equipment is suspected, reorient the device or remove possible sources of interference (for example, cellular phones, radios, etc.) from the room.
- Monitoring electrodes should be placed as far as possible from the disposable device tips when high frequency surgical equipment and physiological monitoring equipment are used simultaneously. Monitoring systems incorporating high frequency current-limiting devices are recommended for use.
- Needle monitoring electrodes are not recommended.
- Activation of a radiofrequency device when not in contact with target tissue or in a position to deliver energy may cause capacitive coupling.
- The patient should not come in contact with metal parts which are earthed (grounded) or which have appreciable capacitance to earth (for example operating table supports, etc.).
- Cables to the surgical electrodes should be positioned so that contact with patient or other leads is avoided.
- CRT11 is recommended if Generator G11 is moved out of the operating room. Maintain control of the generator and cart when moving over thresholds.

Customer Service

Warranty

This warranty and the rights and obligations hereunder shall be construed under and governed by the laws of the State of Ohio, U.S.A.

Ethicon Endo-Surgery warrants this product to be free from defects in material and workmanship under normal use and preventive maintenance for the respective warranty period shown below. Ethicon Endo-Surgery's obligation under this warranty is limited to the repair or replacement, at its option, of any product, or part thereof, which has been returned to Ethicon Endo-Surgery or its distributor within the applicable time period shown below and which examination disclosed, to Ethicon Endo-Surgery's satisfaction, to be defective. This warranty does not apply to any product, or part thereof, that has been: (1) adversely affected due to use with devices manufactured or distributed by parties not authorized by Ethicon Endo-Surgery (2) repaired or altered outside Ethicon Endo-Surgery's factory in a way so as to, in Ethicon Endo-Surgery's judgement, affect its stability or reliability, (3) subjected to improper use, negligence or accident, or (4) used other than in accordance with the design and use parameters, instructions and guidelines for the product or with functional, operational or environmental standards for similar products generally accepted in the industry.

Ethicon Endo-Surgery's products are warranted for the following periods after delivery to the original purchaser:

Generator and power cord	One (1) year, parts and labor
Footswitch	One (1) year, parts and labor
Cart	One (1) year, parts and labor

UNLESS SUPERCEDED BY APPLICABLE LOCAL LAW, THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON THE PART OF ETHICON ENDO-SURGERY AND IS A PURCHASER'S EXCLUSIVE REMEDY. IN NO EVENT SHALL ETHICON ENDO-SURGERY BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES INCLUDING, WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, PROFITS, BUSINESS OR GOODWILL, OTHER THAN AS EXPRESSLY PROVIDED BY A SPECIFIC LAW. Ethicon Endo-Surgery neither assumes

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nor authorizes any other person to assume for it any other liability in connection with the sale or use of any of Ethicon Endo-Surgery products. There are no warranties that extend beyond the terms hereof. Ethicon Endo-Surgery reserves the right to make changes to products built and/or sold by them at any time without incurring any obligation to make the same or similar changes on products previously built and/or sold by them.

Customer Service

Contact the Ethicon Endo-Surgery Customer Service Department or your local representative for any customer or technical support. Call 1-800-USE-ENDO (1-800-873-3636) in the U.S. only.

Chapter 2 - Instructions for Use - HARMONIC Devices

Setup

Caution: Do not block the air vents of the generator to avoid generator overheating.

1 Examine the Generator G11 and the HARMONIC device for damage. Do not use damaged devices.

2 Secure the generator on its cart or any other suitable fixture in the appropriate position.

3 Connect the power cord to the power cord receptacle on the back panel of the generator and to a grounded electrical outlet. The power requirements for the Generator G11 are listed on the label on the back panel of the generator.

4 Connect the footswitch connector to the footswitch receptacle on the back panel of the generator if applicable.

5 Connect the HARMONIC instrument to the Generator G11.

- If the plug looks like the image below, connect the device directly to the Generator G11 receptacle.



Figure 4

- If the plug looks like the image below, use the connector as an interface between the device and the generator.



Figure 5

Caution: Verify that the generator is secured to the cart or any other suitable fixture before powering up.

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6 Turn on the generator using the On/Off switch on the front panel of the generator.

7 The green standby indicator illuminates and the system will run its initiation sequence. A tone is heard during the initiation sequence. When the initiation sequence is complete the test prompt screen appears.

8 Follow the instructions on the screen to run the test.

9 The HARMONIC ready screen appears and the generator is ready for use.

Ready Screen Features

The HARMONIC ready screen has the following features:

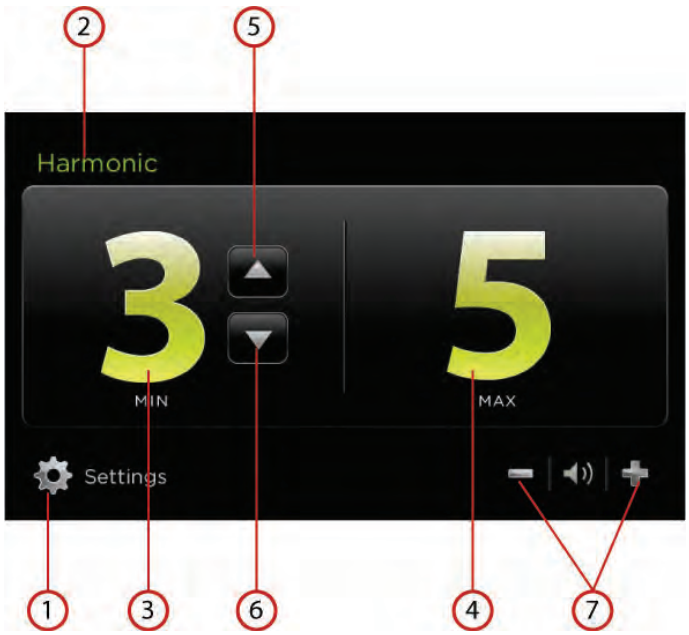


Figure 6

1	SETTINGS	Touch this button to go to the system settings.
2	DEVICE SPECIFICATION	Indicates the device in use.
3	MIN	Indicates the user-adjustable minimum power level setting. When this power level is activated (by footswitch or handswitch), the 'MIN' indicator will flash. The system defaults to 'MIN' power level 3. Refer to the individual instrument package inserts for the recommended minimum power level.
4	MAX	Indicates the maximum power level setting. This setting is always 5. When this power level is activated (by footswitch or handswitch) the 'MAX' indicator will flash.
5	POWER LEVEL INCREASE	Touch this button to increase the minimum (MIN) power setting to the desired level (from 1 to 5). The level chosen will be shown on the screen. The power level may be adjusted when the generator is ready.
6	POWER LEVEL DECREASE	Touch this button to decrease the minimum (MIN) power setting to the desired level (from 1 to 5). The level chosen will be shown on the screen. The power level may be adjusted when the generator is ready.
7	VOLUME	Touch the plus or minus button to adjust the volume of the activation tones. A tone is heard to indicate the volume level selected.

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Operation

Minimum or maximum power is activated from the HARMONIC device or from the footswitch.

Use the left pedal on the footswitch for activating minimum power and use the right pedal for maximum power.

During minimum activation, the MIN area on the generator screen will glow green and pulse. During maximum activation the MAX area will glow green and pulse. As the power is activated, audio feedback is initiated.

The default power level value is 3 for the minimum. Touch the power level increase or the power level decrease button to increase or decrease the level of power to be generated in this mode.

Note: Only the MIN power level setting is adjustable. The MAX power level setting is always set to 5.

Volume

Adjust the volume using the plus or minus button. Default volume setting is 7.

Shutdown

Turn off the generator using the On/Off switch on the front panel of the unit.

The shutdown sequence cannot be initiated during power activation. During shutdown, the generator clears content from the screen, informs the user if 10 or fewer hand piece uses remain for the attached hand piece and displays the shutdown animation.

Settings

Basic Navigation

Touch the 'Settings' button to make adjustments in the system settings and access system information.

The settings screen opens. Scroll down for further options.

Note: If power is activated while in the Settings menu, the Settings window automatically closes and returns to the ready screen.

Touch the close button 'X' to exit from anywhere within the Settings menu. Touch the back arrow to go to the previous menu from the submenu screens.



Figure 7

Display Brightness

Select 'Display Brightness' to see a preview of the ready screen while adjusting the brightness.

Touch the plus or minus button to adjust the brightness.

Touch the back arrow or close button after adjusting the settings to exit. Once a new brightness setting is selected that setting becomes the new system default.

Hand / Foot Activation

Select the handswitch activation or the footswitch activation or both on the 'Hand / Foot Activation' screen during startup. This selection can be changed during use.

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A dot is used to indicate the current setting while a green glow highlights the current selection.

Touch the back arrow or close button after adjusting the settings to exit.

Language

Select the preferred language from the options in the 'Language' screen. There are six language options, English being the default. Once the user selects and confirms the selection of a new language, that language becomes the new system default.

Touch the desired option, a confirmation screen will appear.

Select 'OK' to confirm the language selection or 'Cancel' to cancel the language change.

Hand Piece Test

Select 'Hand Piece Test' to check if the hand piece is functioning properly by installing a test tip and running the test with no instrument attached. Screen instructions and results are given for the specific hand piece to be tested.

System Information

Select 'System Information' to see the high-level information about the generator and the device currently connected to the generator. The hospital staff can use the information to determine if a new hand piece should be ordered. The screen will also allow determination of the currently installed generator software revision.

Biomed Information

'Biomed Information' allows the technicians to access information about each error that has occurred on the generator and allows access to a 'Biomed Mode' display that streams data during instrument use. Touch the back arrow or close button to exit.

Warning

The active blade of a HARMONIC instrument heats the tissue by friction and is intended to supply sufficient friction and shearing effect to cut and coagulate tissue in contact with the active blade. As a result, the user should use caution with the blade, clamp arm, and distal part of the shaft as they may exhibit an elevated temperature. Additional temperature information may be contained in individual instrument instructions for use.

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Chapter 3 - Instructions for Use - ENSEAL Devices

Setup

Caution: Do not block the air vents of the generator to avoid generator overheating.

1 Examine the Generator G11 and the ENSEAL device for damage. Do not use damaged devices.

2 Secure the generator on its cart or any other suitable fixture in the appropriate position.

3 Connect the power cord to the power cord receptacle on the back panel of the generator and to a grounded electrical outlet. The power requirements for the Generator G11 are listed on the label on the back panel of the generator.

4 Connect the footswitch connector to the footswitch receptacle on the back panel of the generator if applicable.

5 Connect the ENSEAL tissue sealing device to the Generator G11. Refer to instrument instructions for use.

- If the plug looks like the image below, connect the device directly to the Generator G11 receptacle.



Figure 8

- If the plug looks like the image below, use the connector as an interface between the device and the generator.



Figure 9

Caution: Verify that the generator is secured to the cart or any other suitable fixture before powering up.

6 Turn on the generator using the On/Off switch on the front panel of the generator.

7 The green standby indicator illuminates and the system will run its initiation sequence. A tone is heard during the initiation sequence. When the initiation sequence is complete the ENSEAL ready screen appears and the generator is ready for use.

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Ready Screen Features

The ENSEAL ready screen has the following features:

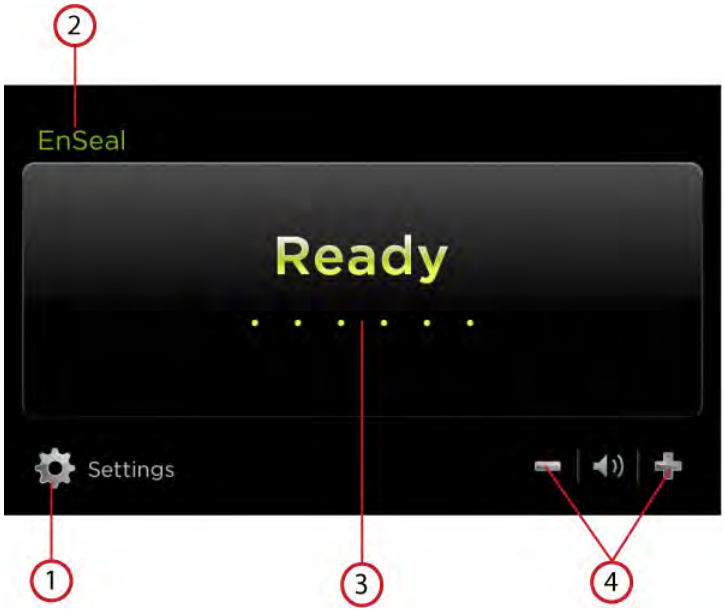


Figure 10

1	SETTINGS	Used to go to the system settings.
2	DEVICE SPECIFICATION	Indicates the device in use.
3	READY	System ready display.
4	VOLUME	Touch the plus or minus button to adjust the volume of the activation tones. A tone is heard to indicate the volume level selected.

Operation

Power is activated from the ENSEAL device or from the left pedal of the footswitch. The ENSEAL device has only one mode of operation. There are no power level settings. When power is activated audio feedback is initiated. When the upper impedance threshold is reached and before the knife has been fully advanced, the audio feedback changes into a higher pitch tone. When both the upper impedance threshold has been reached and the knife has been fully advanced (handle is fully closed), a single tone sounds, indicating a complete cycle. Always advance the knife under power. The single tone for a complete cycle is the only indication of a complete cycle and cut.

Volume

Adjust the volume using the plus or minus button. Default volume setting is 7.

Shutdown

Turn off the generator using the On/Off switch on the front panel of the unit.

The shutdown sequence cannot be initiated during power activation. During shutdown, the generator clears content from the screen and displays the shutdown animation.

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Settings

Basic Navigation

Touch the 'Settings' button to make adjustments in the system setup and access system information.

The settings screen opens. Scroll down for further options.

Note: If power is activated while in the Settings menu, the Settings window automatically closes and returns to the ready screen.

Touch the close button 'X' to exit from anywhere within the Settings menu. Touch the back arrow to go to the previous menu from the submenu screens.

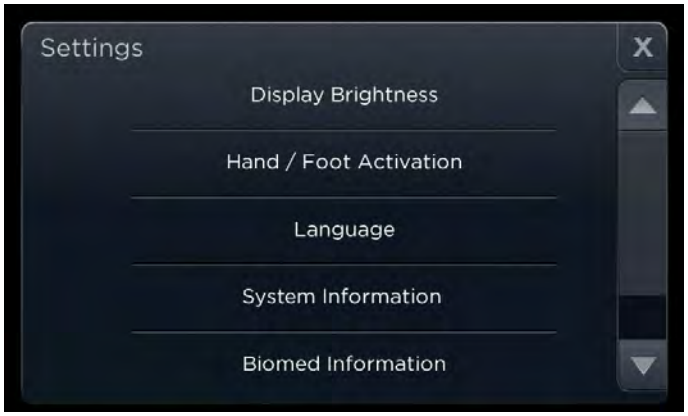


Figure 11

Display Brightness

Select 'Display Brightness' to see a preview of the ready screen while adjusting the brightness.

Touch the plus or minus button to adjust the brightness.

Touch the back arrow or close button after adjusting the settings to exit. Once a new brightness setting is selected that setting becomes the new system default.

Hand / Foot Activation

Select the handswitch activation or footswitch activation or both on the 'Hand / Foot Activation' screen during startup. This selection can be changed during use.

A dot is used to indicate the current setting while a green glow highlights the current selection.

Touch the back arrow or close button after adjusting the settings to exit.

Language

Select the preferred language from the options in the 'Language' screen. There are six language options, English being the default. Once the user selects and confirms the selection of a new language that language becomes the new system default.

Touch the desired option, a confirmation screen will appear.

Select 'OK' to confirm the language selection or 'Cancel' to cancel the language change.

System Information

Select 'System Information' to see the high-level information about the generator and the device currently connected to the generator. The screen will also allow determination of the currently installed generator software revision.

Biomed Information

'Biomed Information' allows the technicians to access information about each error that has occurred on the generator.

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Chapter 4 - Troubleshooting and Screen Guide

General Troubleshooting

Informative

The user interface for the Generator G11 has a number of informative screens to guide the efficient use of the generator. Informative screens will maintain a consistent dark background to differentiate them from the alarm screens shown below.

Alarm System

The Generator G11 includes integrated diagnostics that monitor the operation of the generator and accessories and flash either informative screens or alarms with no delay. In addition to audible alarm sounds, the display of alarms on the front panel is easily observable by the surgeon or nursing staff from the surgical field. All alarms are technical alarms and are based on electrical parameters. There are no physiological alarms that are produced by the Generator G11.

Alarm settings are not adjustable by the operator nor can priority be reassigned. Alarm settings also do not adjust to operator inputs nor do they change through power loss. The Power on Self Test (POST) verifies that the generator is operational. Since the alarms are integrated into the software algorithms responsible for running the appropriate instruments, the POST also verifies alarm operation. Therefore, a separate test for verifying the alarm output is not required. During the POST an audio tone is emitted from the generator so the user can verify that the audio output is operational. Visual output can also be verified through the start up screens. Alarm audio cannot be paused but audio automatically ends when the user discontinues activation of the instrument.

Alarms and other events are logged in the generator. The log is retained after power is removed and is accessed through the biomed screen. There is no reminder signal.

Audio Sound Pressure Levels

- Medium level alarms: Greater than 75 dBA (not adjustable)
- Low level alarms: Within 70 - 75 dBA (not adjustable)

Alarm Definitions

The following alarm priorities are used for the Generator G11. All alarms stop generator output and high priority alarms will take precedence over lower priority alarms. Only one alarm will be displayed at a time since any alarm stops output.

Low Priority Alarms

Requires surgical staff attention for continued, efficient procedural progress. A low priority issue will not generally progress to a hazardous condition even if not addressed promptly but it must be addressed to continue the procedure. The screen shows a solid yellow background with a low priority alarm symbol. A two-tone audio alarm sound accompanies a low priority alarm.

Medium Priority Alarms

Requires prompt surgical staff attention to reduce or mitigate a hazardous condition. Ignoring this alarm can result in a serious injury or death. The screen shows a solid yellow background with a flashing medium priority alarm symbol. A three-tone audio alarm sound accompanies a medium priority alarm.

High Priority Alarms

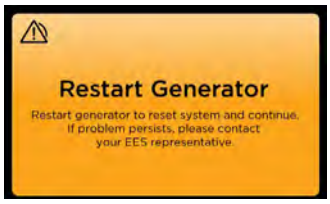
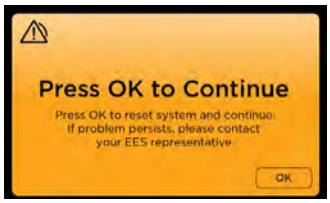
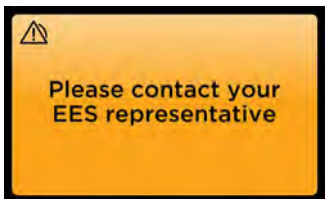
There are no high priority alarm conditions in Generator G11.

The following are the general low priority alarms:

Visual Alarms	Description	Troubleshooting Steps
	Two activation switches are closed in the system. This may be due to a stuck switch or the inadvertent closure of an additional switch.	Reactivate instrument to continue. If the surgical staff has activated only one switch, replace the instrument or footswitch that may have the stuck switch.

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	A system reset is required.	Remove the instrument from the incision and cycle the generator power using the Power On/Off switch on the front of the panel. If problem persists, please send the generator to an authorized Ethicon Endo-Surgery service center.
	A system reset is required.	Press OK to return to the state the system was in when the error occurred. If problem persists, please send the generator to an authorized Ethicon Endo-Surgery service center.
	Indicates an internal error with the cooling fans of the generator.	Please send the generator to an authorized Ethicon Endo-Surgery service center.
	The generator is overheating.	Remove any obstructions from the air vents at the back and bottom of the generator. If the air vents are not blocked and the problem persists return the generator to an authorized Ethicon Endo-Surgery service facility.
	The device requires a generator software upgrade.	Contact your Ethicon Endo-Surgery representative for a software upgrade.
	Any general issue with the system.	Contact your Ethicon Endo-Surgery representative.

HARMONIC Troubleshooting

Note: The following alarms are specific to HARMONIC devices used with Generator G11.

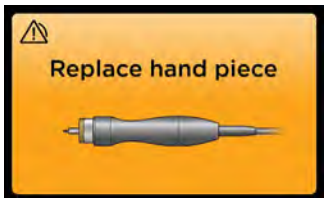
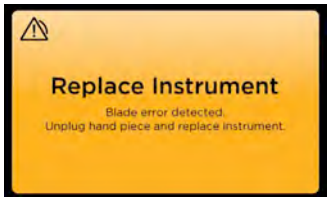
Alarms

The Generator G11 supports the following alarms to help in the identification and troubleshooting of component problems when using a HARMONIC device. The following list is meant as an adjunct to, but not a substitute for clinical judgment and observation.

Other than fuses, there are no operator-serviceable parts in the Generator G11. For replacement or service, contact the Ethicon Endo-Surgery Customer Service Department or your local representative.

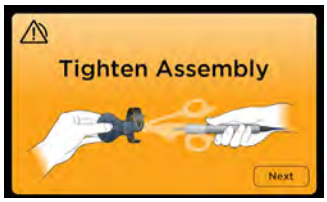
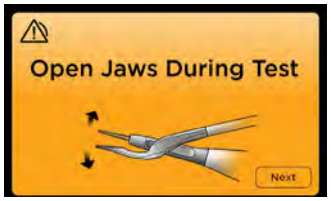
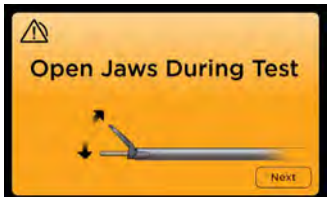
Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Visual Alarms	Description	Troubleshooting Steps
	The hand piece has reached the end of life.	Replace the hand piece. Contact the Ethicon Endo-Surgery Customer Service Department (call 1-800-USE-ENDO (1-800-873-3636) in the U.S. only) or contact your local sales representative to discuss local waste disposal solutions and processes.
		
	The hand piece has failed to perform the internal diagnostic routines and the generator will not be able to operate the hand piece reliably.	Replace the hand piece. Contact the Ethicon Endo-Surgery Customer Service Department (call 1-800-USE-ENDO (1-800-873-3636) in the U.S. only) or contact your local sales representative to discuss local waste disposal solutions and processes.
		
	The instrument has been loaded to the point where output has stopped.	Relax pressure on the instrument or reposition so there is less tissue in the jaws. Release the activation switch and reactivate the instrument to continue.
	This screen is a prelude to further diagnostics. To avoid inadvertent tissue damage during diagnostics the surgeon is guided to remove the instrument from the incision before proceeding.	Remove the instrument from the incision. When the instrument is clear, touch the 'Next' button for further diagnostic guidance.
	The HARMONIC instrument may be damaged and cannot be activated.	Unplug the hand piece and replace the instrument.

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	The instrument may not be properly assembled to the hand piece.	Press the 'Next' button to continue. Re-tighten the instrument. Ensure that one hand is holding the appropriate torque wrench and the other hand is holding the hand piece (not the instrument).
		
	If using shears, keep jaws of device open during test.	Press 'Next' to advance, to retry test with jaws open.
	If using shears, keep jaws of device open during test.	Press 'Next' to advance, to retry test with jaws open.
	Indicates an internal error with the instrument that prevents it from being used.	Unplug the hand piece and replace the instrument. Note: If multiple instruments have indicated an instrument error on the same hand piece, try replacing the hand piece to ensure that the issue is related to the instruments.
	A system reset is required.	Reactivate instrument to reset system and continue.
	Indicates an internal error with the identification circuitry in the instrument. Special circuitry is installed on certain advanced devices to identify the device to the generator and tailor the generator's output to the device.	Unplug hand piece and replace instrument.

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 	Indicates an internal error that may be either with the hand piece or the instrument.	Change hand piece first. Please contact your EES representative to screen current hand piece for errors. If problem persists, unplug hand piece and replace instrument.

ENSEAL Troubleshooting

Note: The following alarms are specific to ENSEAL devices used with Generator G11.

Alarms

The Generator G11 supports the following alarms to help in the identification and troubleshooting of component problems when using an ENSEAL tissue sealing device. The following list is meant as an adjunct to, but not a substitute for clinical judgment and observation.

Other than fuses, there are no operator-serviceable parts in the Generator G11. For replacement or service contact the Ethicon Endo-Surgery Customer Service Department or your local representative.

Visual Alarms	Description	Troubleshooting Steps
	Instrument is being activated on low impedance (thin) tissue or metal (such as staples, clips, retractors, or clamps).	Reposition the instrument jaws and reactivate.
 	The same alarm has triggered three times in a row. There may be an issue in the instrument.	Replace the instrument.
	Indicates an internal issue with the identification circuitry in the instrument. Special circuitry is installed on certain advanced devices to identify the device to the generator and tailor the generator's output to the device.	Replace the instrument.

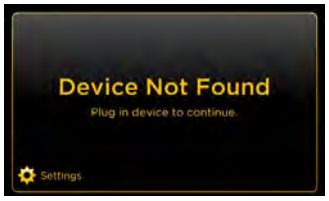
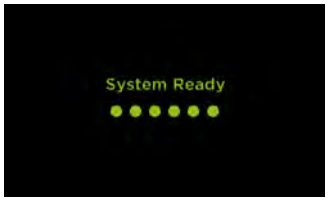
Questions?Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	A system reset is required.	Reactivate instrument to reset system and continue. If problem persists, replace instrument.
	This is a medium priority alarm. The generator cannot deliver energy. (The instrument may cut tissue without a seal if the surgeon advances the knife.)	If the instrument jaws are open, close jaws on tissue and reactivate. If the jaws are closed on tissue and this alarm sounds, do not advance the knife. If the knife is advanced, do not release the instrument. Add additional clamping as necessary to prevent blood loss before releasing the instrument.

Screen Guide

General Screens

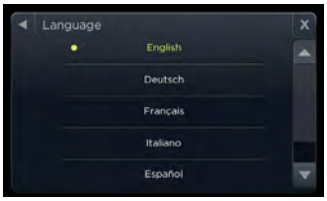
Screen	Description
	Ethicon Endo-Surgery (**Note:** Appears during system startup.)
	Starting Up (**Note:** System is starting up.)
	Device Not Found: Plug in device to continue. (**Note:** Press 'Settings' for Settings Menu.)
	Settings: Hand / Foot Activation Language System Information System Event Log
	System Ready (**Note:** System startup is complete.)

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Hand / Foot Activation:
- Both handswitch and footswitch active
- Only handswitch active
- Only footswitch active



Language:
- English
- German
- French
- Italian
- Spanish



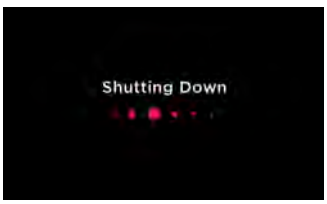
Language:
- Italian
- Spanish
- Russian



Language is now set to (name of language). Cancel to return to the previous language selected.



Identifying Device
(**Note:** System identifying new device just plugged into generator.)



Shutting down
(**Note:** System is shutting down.)

HARMONIC Screens

Screen	Description
	(Number of Uses) Remaining: Replace hand piece after (blank) uses.

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(Number of Uses) Remaining: Replace hand piece after (blank) uses.



Activate instrument for 2 seconds to run test. If using shears, open jaws during test.
(**Note:** Press 'Settings' for Settings Menu.)



Activate instrument for 2 seconds to run test. If using shears, open jaws during test.
(**Note:** Press 'Settings' for Settings Menu).



Testing
(**Note:** Running system test.)



Foot Activation Off
(**Note:** Reactivate with handswitch, or adjust settings. Press 'Settings' for Settings Menu.)



Hand Activation Off
(**Note:** Reactivate with footswitch, or adjust settings. Press 'Settings' for Settings Menu.)



Relax Pressure on Blade.
(**Note:** Press 'Settings' for Settings Menu.)

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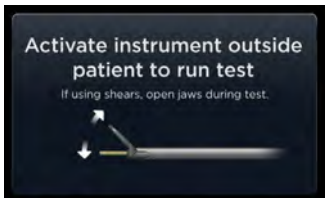
Clean Blade. Remove any tissue which may be lodged inside end of instrument sheath.
(**Note:** Press 'Next' to advance.)



Tighten Assembly
(**Note:** Press 'Next' to advance.)



Tighten Assembly
(**Note:** Press 'Next' to advance.)



Activate instrument outside patient to run test. If using shears, open jaws during test.



Activate instrument outside patient to run test. If using shears, open jaws during test.



HARMONIC Settings:
- Display Brightness
- Hand / Foot Activation
- Language
- Hand Piece Test
- System Information



HARMONIC Settings:
- Hand Piece Test
- System Information
- Biomed Information

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HARMONIC Display Brightness.



Hand Piece Test. Assemble Test Tip to begin.
(**Note:** Press 'Test' to run test.)



Hand Piece Test. Assemble Test Tip to begin.
(**Note:** Press 'Test' to run test.)



Test Complete

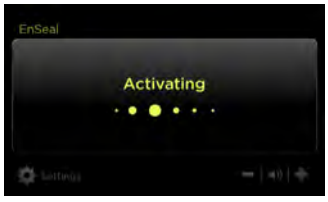


Hand Piece Test Results:
- Hand Piece Uses Remaining
- Phase Margin
- Impedance
- Hand Piece is Functioning Normally



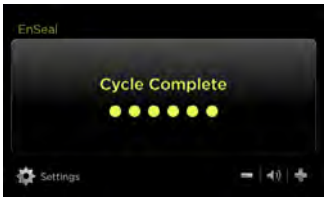
System Information:
- Software Version
- Hand Piece
- Hand Piece Uses Remaining

ENSEAL Screens

Screen	Description
	Activating (**Note:** Power is being activated.)

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

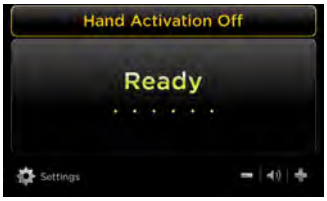
Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018



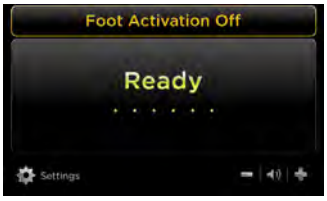
Cycle Complete
(**Note:** Cut is complete. Press 'Settings' for Settings Menu.)



Activation Cycle Timed Out: Reactivate
(**Note:** Cycle Complete was not reached. Reactivate to continue. Press 'Settings' for Settings Menu.)



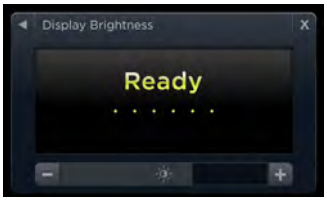
Hand Activation Off: Ready
(**Note:** Reactivate with footswitch, or adjust settings. Press 'Settings' for Settings Menu.)



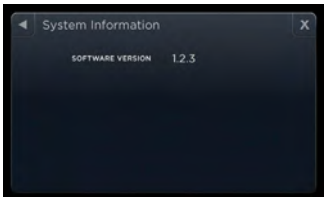
Foot Activation Off: Ready
(**Note:** Reactivate with handswitch, or adjust settings. Press 'Settings' for Settings Menu.)



ENSEAL Settings:
- Display Brightness
- Hand / Foot Activation
- Language
- System Information
- Biomed Information



ENSEAL Display Brightness: Ready.



System Information: Software Version.

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

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Chapter 5 - Cleaning, Disinfection, Preventive Maintenance and Repair

Electrical Safety Checks

- The hospital is responsible for ensuring that the unit has an electrical safety check performed by qualified service personnel at least once a year.
- Do not remove the cover of the Generator G11. Removing the cover voids the Generator G11 warranty.

Cleaning and Disinfection Instructions

Before cleaning, thoroughly inspect the device(s) for any signs of damage, cracks, or improper mechanical function. Do not use the device(s) if there are signs of damage. Discard and replace device or send device to an authorized Ethicon Endo-Surgery service facility for repair where appropriate, if damage or degradation is present.

- Operators in North America should refer to appropriate sections of *AORN Standards & Recommended Practices* for additional guidance on cleaning. All other localities should refer to appropriate guidelines.
- The operator must qualify cleaning effectiveness when deviating from the instructions in this manual.

Generator G11 and Touchscreen

Cleaning

Clean the generator and the touchscreen following the hospital protocol. Before cleaning, turn the generator main power off and unplug the power cord from the grounded electrical outlet.

Warning: Spilling or spraying fluids on or into the generator or immersing the generator may result in damage to the device and creates a risk of shock or fire.

Proceed with cleaning as follows:

1. Prepare a neutral pH detergent or a neutral pH enzymatic detergent according to the manufacturer's directions.
2. Use a soft, clean cloth lightly moistened with the cleaning solution to manually clean the surfaces. Pay special attention to cracks and crevices.
3. Wipe thoroughly using a soft, clean cloth lightly moistened with warm tap water.
4. Dry with a soft, clean cloth.

Disinfecting

If the generator becomes contaminated with blood or bodily fluids, it must be wiped down with a disinfectant before reuse. The following chemical disinfectants are approved for use with the generator: Isopropyl Alcohol - 70%, Sodium hypochlorite solutions (0.25% - 0.50%), Cidex OPA, Dispatch, and Gigasept FF.

Disinfectants should be prepared and used according to the manufacturer's recommendations for use, concentration, and contact time.

The use of disinfectants other than those specified in these instructions should be assessed for material compatibility before using. At a minimum, intermediate level* disinfectants should be used. Technical data sheets are typically available on the manufacturer's web site to assist in this assessment.

* "Intermediate level" is a classification applicable in the US. Intermediate disinfectants kill viruses, mycobacteria, fungi, and vegetative bacteria.

Any disinfection process including tools and solutions may influence the wear and tear of the device or equipment. In some instances, changing to another disinfectant may be required.

Within the applied decontamination process ensure that the detergent or disinfectant residuals are completely removed after wipe down. If detergent or disinfectant residuals remain, moisten a soft, clean cloth with purified or deionized water and wipe down affected areas (multiple wipes may be required to remove any remaining residue) or refer to the manufacturer's recommendations for the removal of the disinfectant residuals.

Connectors (HGA11 and EGA11)

Cleaning

Warning: Spilling or spraying fluids on or into the connectors or immersing the connectors may result in damage to the connectors.

Proceed with cleaning as follows:

1. Prepare a neutral pH detergent or a neutral pH enzymatic detergent according to the manufacturer's directions.
2. Use a soft, clean cloth lightly moistened with the cleaning solution to manually clean the surfaces. Pay special attention to cracks and crevices.

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3. Wipe thoroughly using a soft, clean cloth lightly moistened with warm tap water.
4. Dry with a soft, clean cloth.

Note: Disinfection with the listed chemicals may cause discoloration or wet spots on the central metallic post of the connector that interfaces with the Generator G11 receptacle. Discoloration or wet spots on the central metallic post of the connector should not affect the connector function.

Disinfecting

If the connectors become contaminated with blood or bodily fluids, they must be wiped down with a disinfectant before reuse. The following chemical disinfectants are approved for use with the connectors: Isopropyl Alcohol - 70%, Sodium hypochlorite solutions (0.25% - 0.50%), Cidex OPA, Dispatch, and Gigasept FF.

Disinfectants should be prepared and used according to the manufacturer's recommendations for use, concentration, and contact time.

The use of disinfectants other than those specified in these instructions should be assessed for material compatibility before using. At a minimum, intermediate level* disinfectants should be used. Technical data sheets are typically available on the manufacturer's web site to assist in this assessment.

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Cart (CRT11)

Cleaning

Proceed with cleaning as follows:

1. Prepare a neutral pH detergent or a neutral pH enzymatic detergent according to the manufacturer's directions.
2. Use a soft, clean cloth lightly moistened with the cleaning solution to manually clean the surfaces. Pay special attention to cracks and crevices.
3. Wipe thoroughly using a soft, clean cloth lightly moistened with warm tap water.
4. Dry with a soft, clean cloth.

Disinfecting

If the cart becomes contaminated with blood or bodily fluids, it must be wiped down with a disinfectant before reuse. The following chemical disinfectants are approved for use with the cart: Isopropyl Alcohol - 70%, Sodium hypochlorite solutions (0.25% - 0.50%), Cidex OPA, Dispatch, and Gigasept FF.

Disinfectants should be prepared and used according to the manufacturer's recommendations for use, concentration, and contact time.

The use of disinfectants other than those specified in these instructions should be assessed for material compatibility before using. At a minimum, intermediate level* disinfectants should be used. Technical data sheets are typically available on the manufacturer's web site to assist in this assessment.

* "Intermediate level" is a classification applicable in the US. Intermediate disinfectants kill viruses, mycobacteria, fungi, and vegetative bacteria.

Any disinfection process including tools and solutions may influence the wear and tear of the device or equipment. In some instances, changing to another disinfectant may be required.

Within the applied decontamination process ensure that the detergent or disinfectant residuals are completely removed after wipe down. If detergent or disinfectant residuals remain, moisten a soft, clean cloth with purified or deionized water and wipe down affected areas (multiple wipes may be required to remove any remaining residue) or refer to the manufacturer's recommendations for the removal of the disinfectant residuals.

Footswitch (FSW11)

Cleaning

Note: Always keep the generator connector dry.

Proceed with wipe-down cleaning as follows:

1. Prepare a neutral pH detergent or a neutral pH enzymatic detergent according to the manufacturer's directions.

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2. Use a soft, clean cloth lightly moistened with the cleaning solution to manually clean the surfaces. Pay special attention to cracks and crevices.
3. Wipe thoroughly using a soft, clean cloth lightly moistened with warm tap water.
4. Dry with a soft, clean cloth.

If necessary, the footswitch may be immersed for cleaning as follows:

1. Immerse the footswitch and cordset (not the generator connector) in a neutral pH enzymatic detergent, prepared according to the manufacturer's recommendations.
2. Use a soft bristle brush or soft, clean cloth to manually clean the device in the detergent solution. Pay special attention to cracks and crevices.
3. Rinse off detergent thoroughly using a soft clean cloth soaked with warm tap water or by placing the footswitch under running lukewarm tap water.
4. Dry the device with a clean absorbent cloth.

Disinfecting

If the footswitch becomes contaminated with blood or bodily fluids, it must be wiped down with a disinfectant or immersed in disinfectant before reuse. The following chemical disinfectants are approved for use with the footswitch: Isopropyl Alcohol - 70%, Sodium hypochlorite solutions (0.25% - 0.50%), Cidex OPA, Dispatch, and Gigasept FF.

Disinfectants should be prepared and used according to the manufacturer's recommendations for use, concentration, and contact time.

The use of disinfectants other than those specified in these instructions should be assessed for material compatibility before using. At a minimum, intermediate level* disinfectants should be used. Technical data sheets are typically available on the manufacturer's web site to assist in this assessment.

* "Intermediate level" is a classification applicable in the US. Intermediate disinfectants kill viruses, mycobacteria, fungi, and vegetative bacteria.

Any disinfection process including tools and solutions may influence the wear and tear of the device or equipment. In some instances, changing to another disinfectant may be required.

Within the applied decontamination process ensure that the detergent or disinfectant residuals are completely removed after wipe down or immersion. If detergent or disinfectant residuals remain, moisten a soft, clean cloth with purified or deionized water and wipe down affected areas (multiple wipes may be required to remove any remaining residue), run affected areas under running lukewarm tap water or refer to the manufacturer's recommendations for the removal of the disinfectant residuals.

Other Instruments and Accessories

For other reusable accessories not listed in this manual consult the appropriate instructions for use for guidance on disinfecting and sterilization, if required.

Maintenance and Repair

Periodic calibration is not required for Generator G11. Periodic check of output using GEN11VK is recommended per facility guidelines. Service of Generator G11 would be required if GEN11VK shows the generator is out of tolerance. See GEN11VK Instructions For Use for guidance on performing the output check. For servicing activities, Generator G11 may also be returned to an authorized Ethicon Endo-Surgery service facility at any time.

The Generator G11 contains a Potential Equalization Terminal on the back panel. This is provided for compatibility with other medical systems requiring such connections. This conductor is not intended for protective earthing.

The software revision may be displayed on the biomed screen in the user interface.

Disposing of Ethicon Endo-Surgery Generator G11 (Environmental Protection)

The Generator G11 and accessories must not be disposed of at the end of life with other waste. To recycle the waste equipment, get return instructions from the Ethicon Endo-Surgery Customer Service Department (call 1-800-USE-ENDO (1-800-873-3636) in the U.S. only) or contact your local sales representative to discuss local waste disposal solutions and processes. Generator G11 poses disposal risks similar to consumer electronics such as computers. There are no radioactive substances, batteries, or hazardous liquids that may leak in Generator G11.

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Chapter 6 - Conformance to Standards

The Generator G11 conforms to the following international standards:

EN (IEC) 60601-1 (with Canadian and US National Deviations)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN (IEC) 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN (IEC) 60601-2-2	Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment
EN (IEC) 60601-1-8	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

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

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English

Appendix

System Specifications

Main Fuses	T5AL 250 V (Time-delay, 5 Amp, glass body, 5x20 mm package size, quantity: 2)
Degree of Protection Against Electric Shock	Type CF applied part consisting of the HARMONIC or ENSEAL instruments
Class of Protection Against Electric Shock	Class 1
Ingress Protection G11 Enclosure Ingress Protection G11 Footswitch	IP21 IP68
Main Input	100 - 240 V ~, 50/60 Hz, 500 VA
Output	**ENSEAL Output:** Bipolar, no neutral electrode required 100 VAC RMS maximum 135 watts maximum (rated load 15 ohms) 300 - 490 kHz (330 kHz unless otherwise marked in instrument IFU) **HARMONIC Output:** 150 VAC RMS maximum 35 watts continuous 30 - 80 kHz (55.5 kHz unless otherwise marked in instrument IFU)
Ambient Operating Conditions	Temperature: 15 °C to 27 °C Humidity: 30% - 75% non-condensing Atmospheric Pressure Range: 700 hPa - 1060 hPa
Transport and Storage Conditions	Temperature: -35 °C to +54 °C Humidity: 10% - 95% non-condensing Atmospheric Pressure Range: 700 hPa - 1060 hPa
Weight	Generator: 5.9 kg Cart: 16.8 kg Footswitch: 3.6 kg
Overall Dimensions	Generator: 35.0 cm x 35.5 cm x 13.6 cm Cart: 48.0 cm x 56.2 cm x 95.3 cm Footswitch: 34.2 cm x 19.0 cm x 10.4 cm
Power Cord	**North American removable power cord set** with the following characteristics: Plug Style: NEMA 5-15 (clear) North American Hospital Grade Receptacle: IEC 60320 C13 with straight non-angled cord entry Cord Length: 4.6 meters nominal Current Rating: 13A Voltage Rating: 125 VAC minimum Wiring Code: North American Cordage Description: SJT (UL) or SJT (CSA) Conductors: 16 AWG 3C Agency Approvals Required: UL and CSA **International removable power cord set** with the following characteristics: Plug Style: as needed by particular country requirements Receptacle: IEC 60320 C13 with straight non-angled cord entry Cord Length: 2.44 - 4.6 meters nominal Current Rating: 10A Minimum conductor size cross-sectional area: 1.0 mm^2 copper Voltage Rating: 250 VAC minimum Wiring: International Cordage Type: HAR Item to have certification by at least one of the following agencies: VDE, ASTA, SEMKO, KEMA, LCIE, DFT, IMQ, SEV

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

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Electromagnetic Compatibility (EMC)

The Generator G11 requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and used in accordance with the EMC information provided in this guide. The Generator G11 is intended for use in the electromagnetic environments specified below.
Caution: Ensure that the Generator G11 is used only in these environments.

Electromagnetic Emissions

Emissions Test	Compliance	Guidance
RF emissions CISPR 11	Group 1 (per IEC 60601-2-2:2009)	The Generator G11 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Generator G11 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic Immunity Guidance

For electromagnetic immunity, essential performance is: activation tones are coupled with energy output, energy output ceases when activation switches are opened, and no energy output without activation switch closure.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge IEC 61000-4-2	± 6kV Contact ± 8kV Air	± 6kV Contact ± 8kV Air	Relative humidity should be at least 30%.
Electrical fast Transient/ Burst IEC 61000-4-4	± 2 kV on Power Supply Lines ± 1 kV on Input/Output Lines	± 2 kV on Power Supply Lines ± 1 kV on Input/Output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	± 1kV Differential Mode ± 2kV Common Mode	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency Magnetic Fields IEC 61000-4-3	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

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Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Voltage Dips, Short Interrupts, and Variations on Power Supply Lines IEC 61000-4-11	<5% U_T (95% dip in U_T for 0.5 cycles) <40% U_T (60% dip in U_T for 5 cycles) <70% U_T (30% dip in U_T for 25 cycles) <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (95% dip in U_T for 0.5 cycles) <40% U_T (60% dip in U_T for 5 cycles) <70% U_T (30% dip in U_T for 25 cycles) <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Generator G11 requires continued operation during power mains interruptions, it is recommended that the Generator G11 be powered from an uninterruptible power supply or a battery.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Generator G11, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note: At 80 MHz and 800 MHz, the higher frequency range applies.
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 4,066 MHz to 4,070 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

Recommended separation distances between portable and mobile RF communications equipment and the Generator G11

The Generator G11 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Generator G11 can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile

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

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RF communications equipment (transmitters) and the Generator G11 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.0	1.20	1.20	2.30
10	3.79	3.79	7.27
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Go to *www.e-ifu.com* for latest revision of service manual.

	Footswitch
	Non-ionizing Radiation
	Equipotential Ground Lug
	Electrical and Electronic equipment. Return waste to a collection system or treatment and recycling facilities. Applicable in the EU. Follow decontamination instructions before returning waste.
	Authorized Representative in the European Community
	Manufacturer
	Power On/Off Switch

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

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	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Keep Dry
	Date of Manufacture
	Reorder Number
	Serial Number
	Authorized Representative in the USA
	Non-sterile
	CF Applied Part (Device Connector)
	The electronic information product (EIP) has met the requirements set forth by the People's Republic of China for marking of EIPs, and can be used during its environmental protection use period of 50 years. After the environmental protection period has expired, the EIP should be recycled. Applicable in the People's Republic of China.
	Fuse
	Product is certified by a Nationally Recognized Testing Laboratory.
	Consult the Generator G11 Operator's Manual.

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

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	Refer to instruction manual/booklet for information related to safety.
	Recyclable Packaging
	Relative Humidity
	Temperature
	Low Alarm
	Medium Alarm

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

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FDA/CDRH/DCC
MAY 23 2016
RECEIVED

ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

K160752/S001

May 20, 2016

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

RE: **K160752**

Harmonic HD1000i Shears 20 cm Length
Harmonic HD1000i Shears 36 cm Length

Dear Mehmet:

Attached, please find the response to the questions you raised in your request for additional information dated May 9th, 2016. An eCopy, which is an exact duplicate of the paper copy, is also provided herein.

If there are any questions, please contact me at (513) 337-1281 or by email at Dlocke1@its.jnj.com. Thank you kindly for your time.

Sincerely,

David M. Locke, MS, DRSc, RAC
Senior Regulatory Affairs Program Lead
Ethicon (Energy)

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

ETHICON

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

May 20, 2016

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

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Harmonic HD1000i Shears 36 cm Length

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David M. Locke, MS, DRSc, RAC
Senior Regulatory Affairs Program Lead
Ethicon (Energy)

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

Records processed under FOIA Request 2016-8748. Released by CDRH on 9/13/2018/2018

Response to Deficiency List

Indications for use

1. (b) (4) Deficiency Responses

[redacted]

Ethicon Response: Please see the updated indication below in which "energy-aided dissection" has been removed. An updated IFU can be found in <u>Appendix A</u>.

Indications for Use
(b) (4) Deficiency Responses [redacted]

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

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Performance Testing:

2. (b) (4) Deficiency Responses

(b) (4) Deficiency Responses

3. (b) (4) Deficiency Responses

(b) (4) Deficiency Responses

Cleaning, Disinfection, Sterilization, Shelf-Life and Reuse

4. (b) (4) Deficiency Responses

Ethicon Response:

Sterilization Validation -

(b) (4) Deficiency Responses

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

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(b) (4) Deficiency Responses

[redacted]

Electrical Safety and EMC

(b) (4) Deficiency Responses

[redacted]

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

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Appendix A

Please see the updated IFU provided below.

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

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Appendix B

(b) (4)

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

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Appendix C

(b) (4) Deficiecy Response

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 29, 2016

Ethicon Endo-Surgery, LLC
% Mr. David Locke
Senior Regulatory Affairs Program Lead
Ethicon Endo-surgery, LLC
475 Calle C
Guaynabo, PR 00969

Re: K160752
Trade/Device Name: Harmonic HD 1000i Shears 20 cm Length, Harmonic HD 1000i Shears 36 cm Length
Regulatory Class: Unclassified
Product Code: LFL
Dated: May 20, 2016
Received: May 23, 2016

Dear Mr. Locke:

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.

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education 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 Industry and Consumer Education 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,

Jennifer R. Stevenson
-A

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

Enclosure

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 29, 2016

Ethicon Endo-Surgery, LLC
% Mr. David Locke
Senior Regulatory Affairs Program Lead
Ethicon Endo-surgery, LLC
475 Calle C
Guaynabo, PR 00969

Re: K160752
Trade/Device Name: Harmonic HD 1000i Shears 20 cm Length, Harmonic HD 1000i Shears 36 cm Length
Regulatory Class: Unclassified
Product Code: LFL
Dated: May 20, 2016
Received: May 23, 2016

Dear Mr. Locke:

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.

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education 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 Industry and Consumer Education 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,

Jennifer R. Stevenson
-A

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

Enclosure

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160752

Device Name
HARMONIC HD 1000i Shears 20 cm Length, HARMONIC HD 1000i Shears 36 cm Length

Indications for Use *(Describe)*
The Harmonic HD 1000i Shears instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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PRAStaff@fda.hhs.gov

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Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

510(k) Summary

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

Contact David Locke, DRSc, MS, RAC
Senior Regulatory Affairs Program Lead
Ethicon Endo-Surgery, Inc.
Telephone: (513) 337-1281
Email: dlocke1@its.jnj.com

Date Prepared

June 27, 2016

Device Name

Trade Name: HARMONIC HD 1000i Shears 20 cm Length, HARMONIC HD 1000i Shears 36 cm Length

Common Name: Instrument, Ultrasonic Surgical

Classification Name

Instrument, Ultrasonic Surgical (Unassigned, Product Code: LFL)

Regulatory Class

Unclassified

Predicate Device

HARMONIC ACE®+ Shears with Advanced Hemostasis, cleared under K132612 on October 17th, 2013

Device Description

The HARMONIC HD 1000i Shears are a sterile, single patient use device used for dissection, grasping, coagulation, and cutting between the blade and clamp arm. It consists of an ergonomic grip housing assembly with two hand control buttons: 1) Energy button for power levels 1-5 and, 2) Energy with Advanced Hemostasis button for large vessel sealing. The device is available in two shaft lengths, 20 cm and 36 cm, and both device shafts can be rotated continuously to facilitate visualization and access to targeted tissue.

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

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An integrated audible and tactile mechanism in the grip housing indicates full trigger closure. The device has a clamp arm and coated curved blade that is designed to work through a 5 mm trocar, through a 5 mm reducer cap in a larger diameter trocar, or through an incision without the use of a trocar. The blade used in the HARMONIC HD 1000i Shears has a slightly different blade design than that of the predicate device, the HARMONIC ACE+ Shears with Advanced Hemostasis (cleared under K132612 on October 17, 2013), and is also slightly longer and more tapered than the predicate device. Additionally, two dashes have been added to the device which are intended to represent relative vessel size.

The distal/front Energy button is indicated for vessels up to 5 mm in diameter. The Energy with Advanced Hemostasis button (the Green button), which is found on the side of the device handle, is designed for larger vessels and is indicated for vessels up to 7 mm in diameter. The device utilizes Adaptive Tissue Technology (the technological characteristics of which were first cleared under K120729 on May 17, 2012). This technology provides the generator with the ability to identify and monitor the instrument during use.

The HARMONIC HD 1000i Shears are designed for use exclusively with the Ethicon Generator 11 (GEN11).

Indications for Use

Indications
The Harmonic HD 1000i Shears instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis.

Contraindications

- *The instruments are not indicated for incising bone.*
- *The instruments are not intended for contraceptive tubal occlusion.*

Technological Characteristics

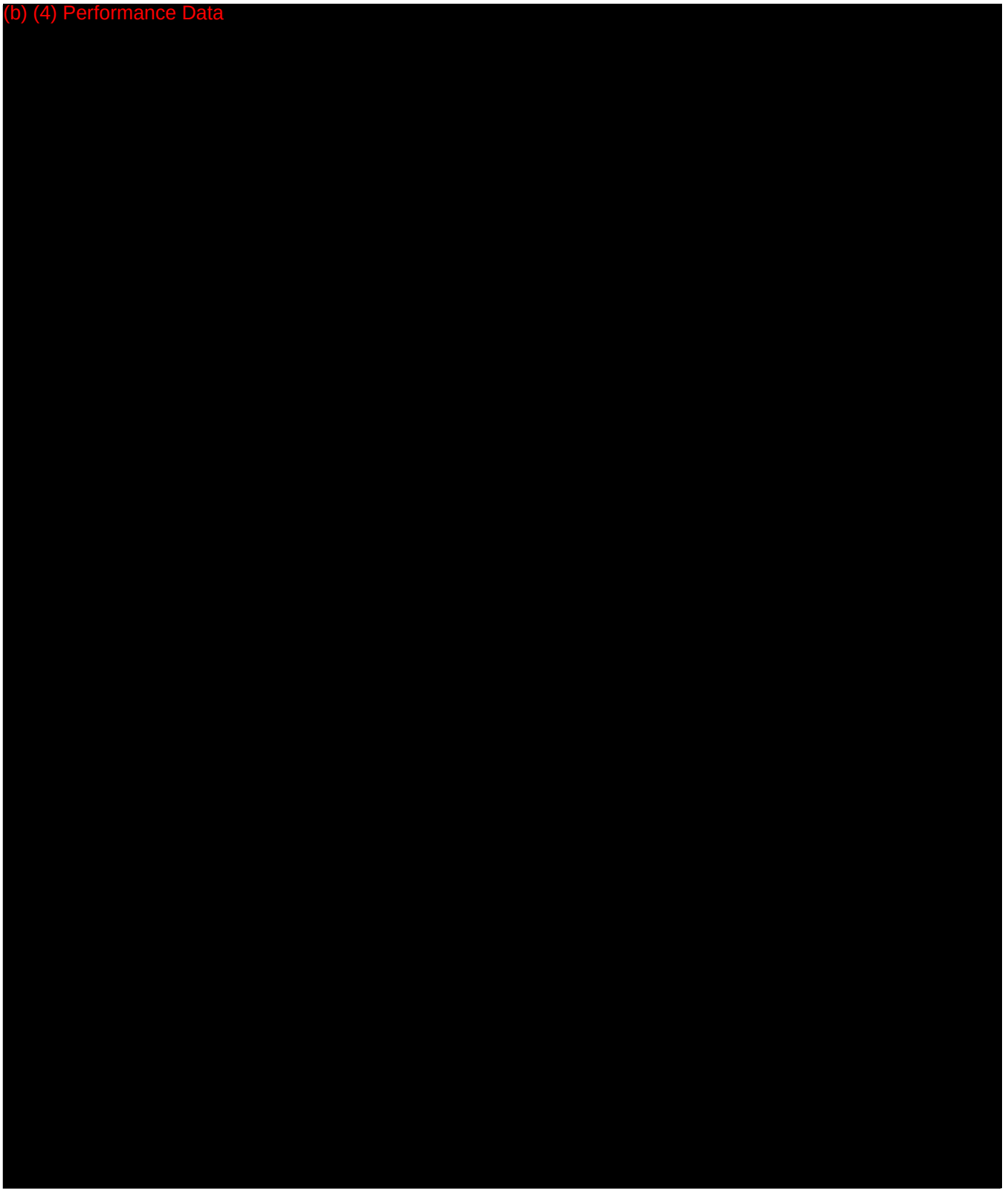
The Ethicon Endo-Surgery HARMONIC HD 1000i Shears incorporate the same technological characteristics as that of the ultrasonic predicate device, HARMONIC ACE+ Shears with Advanced Hemostasis. Both the subject and predicate devices use an EEPROM memory chip that stores device identification, usage tracking, and operating parameters for use by the Generator G11 that provides power for the HARMONIC HD 1000i Shears. Further, both devices have an ergonomic grip housing assembly which allows for manual closure of the jaw and the devices contain buttons which allow for the manual application of energy. To as where the predicate HARMONIC ACE+ Shears with Advanced Hemostasis contains three buttons allowing for manual energy activation, the subject HARMONIC HD 1000i Shear only contains two buttons, allowing for manual energy activation.

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

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Performance Data

(b) (4) Performance Data



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(b) (4) Performance Data

[redacted]

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510(k) Summary

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Contact David Locke, DRSc, MS, RAC
Senior Regulatory Affairs Program Lead
Ethicon Endo-Surgery, Inc.
Telephone: (513) 337-1281
Email: dlocke1@its.jnj.com

Date Prepared

June 27, 2016

Device Name

Trade Name: HARMONIC HD 1000i Shears 20 cm Length, HARMONIC HD 1000i Shears 36 cm Length

Common Name: Instrument, Ultrasonic Surgical

Classification Name

Instrument, Ultrasonic Surgical (Unassigned, Product Code: LFL)

Regulatory Class

Unclassified

Predicate Device

HARMONIC ACE®+ Shears with Advanced Hemostasis, cleared under K132612 on October 17th, 2013

Device Description

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The distal/front Energy button is indicated for vessels up to 5 mm in diameter. The Energy with Advanced Hemostasis button (the Green button), which is found on the side of the device handle, is designed for larger vessels and is indicated for vessels up to 7 mm in diameter. The device utilizes Adaptive Tissue Technology (the technological characteristics of which were first cleared under K120729 on May 17, 2012). This technology provides the generator with the ability to identify and monitor the instrument during use.

The HARMONIC HD 1000i Shears are designed for use exclusively with the Ethicon Generator 11 (GEN11).

Indications for Use

Indications
The Harmonic HD 1000i Shears instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis.

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Performance Data

(b) (4) Performance Data

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Date Prepared

June 27, 2016

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Classification Name

Instrument, Ultrasonic Surgical (Unassigned, Product Code: LFL)

Regulatory Class

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Technological Characteristics

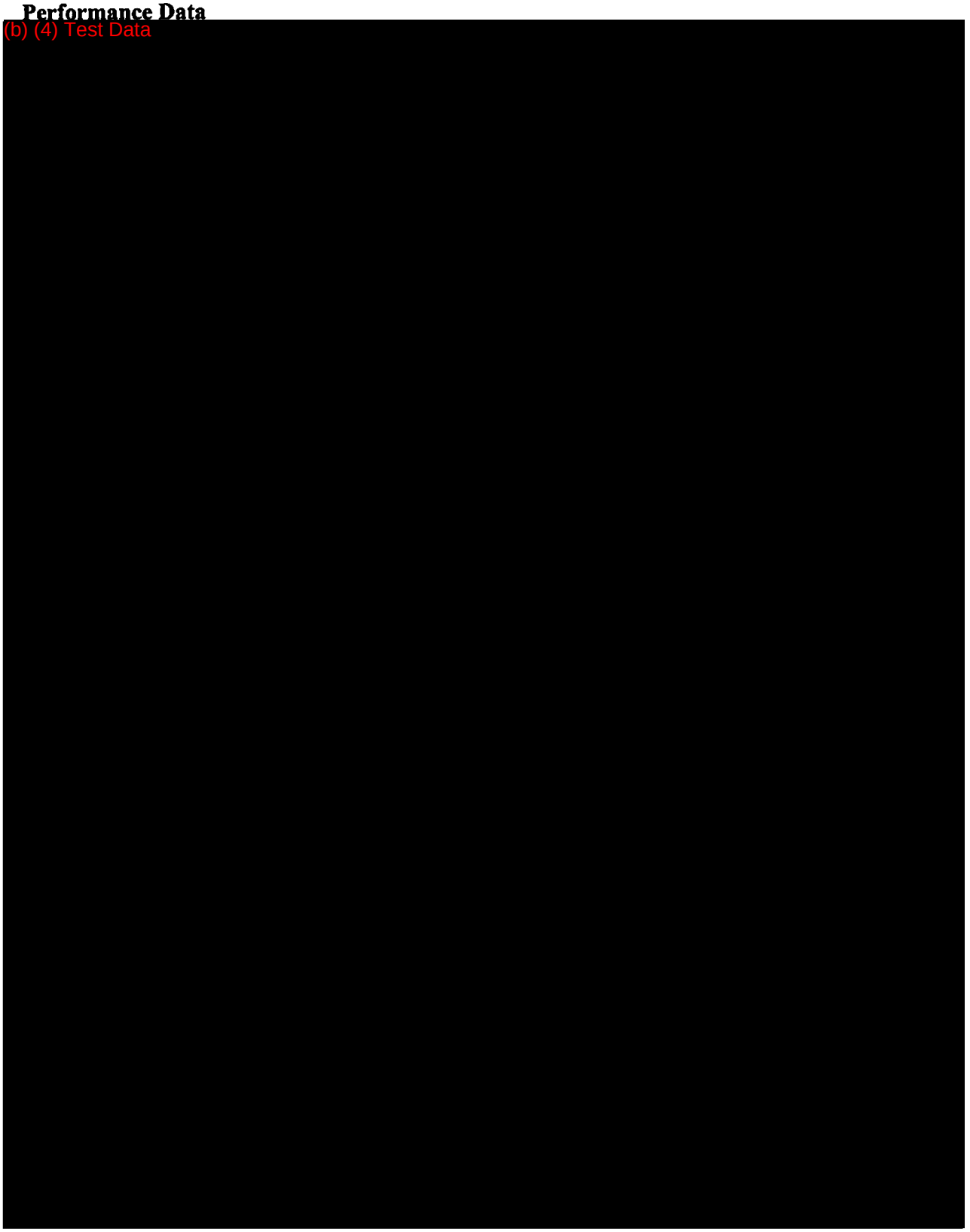
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Performance Data

(b) (4) Test Data



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(b) (4) Test Data

[redacted]

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160752

Device Name
HARMONIC HD 1000i Shears 20 cm Length, HARMONIC HD 1000i Shears 36 cm Length

Indications for Use *(Describe)*
The Harmonic HD 1000i Shears instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis.

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)

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Food and Drug Administration

Indications for Use

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Department of Health & Human Services
Food and Drug Administration

Center for Devices and Radiological Health
Office of Device Evaluation & Office of In-Vitro Diagnostics and Radiological Health

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K160752 Date Received by DCC: 03/18/2016

Lead Reviewer: Mehmet A. Kosoglu, Ph.D.

Branch: GSDB2 Division: DSD Center/Office: CDRH/ODE

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

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X		
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."	X		
Comments:			
3) If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."			X
Comments:			

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X		
Comments:			
5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X	
Comments:			
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm If no clinical studies have been submitted, mark "N/A."			X
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
- If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
- If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
- If the answer to 6 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.

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

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Organizational Elements

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

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	X		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
3) All pages of the submission are numbered.	X		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special).	X		
Comments:			

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X				
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name	X				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X				
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format. (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*	X				
4) Submission contains a 510(k) Summary or 510(k) Statement.	X				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format.* *(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*	X				
6) Submission is a Class III 510(k) device.			X		
7) Submission contains clinical data			X		
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	X				
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.			X		
B. Device Description					
9) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.			X		
10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	X				
11) The submission includes descriptive information for the device, including the following:					
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	X				
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X				
c) A list and description of each device for which clearance is requested.	X				

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	X				
12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.			X		
C. Substantial Equivalence Discussion					
13) Submitter has identified a predicate device(s), including the following information:					
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*	X				
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	X				
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
a) Indications for Use	X				
b) Technology, including features, materials, and principles of operation	X				
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
15) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	X				
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X				
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X				
16) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X				

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

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
17) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements").	X				
18) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device.			X		
19) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X		
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that the device, and/or accessories, and/or components are: (one of the below must be checked)					
X Provided sterile, intended to be single-use					
Requires processing during its use-life					
Non-sterile when used (and no processing required)					
Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
Sterility status not needed for this device (e.g., software-only device)					
Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.*					
20) Assessment of the need for cleaning and subsequent disinfection or sterilization information					
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X				
b) Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected.			X		
c) Identification of device, and/or accessories, and/or components that are reusable.			X		
21) If the device, and/or accessory, and/or a component is provided sterile:					
a) Sterilization method is stated for each component (including dose for radiation sterilization).	X				
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).	X				
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	X				
d) Sterility Assurance Level (SAL) is stated.	X				

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
e) Submission includes description of packaging.	X				
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).			X		
22) If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected:			X		
23) The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.			X		
F. Shelf Life					
24) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	X				
25) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	X				
26) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	X				
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that there: (one of the below must be checked)					
X Are direct or indirect patient-contacting components.					
Are no direct or indirect patient-contacting components.					
Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
Patient contact information not needed for this device (e.g., software-only device)					
Patient contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
27) Submission includes a list identifying each of patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	X				
28) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter)	X				

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
29) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X				
H. Software					
Submission states that the device: (one of the below must be checked)					
	Does contain software/firmware				
X	Does not contain software/firmware				
	Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)				
	Software/firmware information not needed for this device (e.g., surgical suture, condom)				
	Software/firmware information is needed or need unclear				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
I. Electrical Safety and EMC					
Electrical Safety Submission states that the device: (one of the below must be checked)					
X	Does require electrical safety evaluation				
	Does not require electrical safety evaluation				
	Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)				
	Electrical safety information not needed for this device (e.g., surgical suture, condom)				
	Electrical safety information is needed or need unclear				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
32) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard), **OR** Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	X				
EMC Submission states that the device: (one of the below must be checked)					
X	Does require EMC evaluation				

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

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
Does not require EMC evaluation					
Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
EMC information not needed for this device (e.g., surgical suture, condom)					
EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
33) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) **OR** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	X				
J. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.					
34) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions.	X				
a) Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	X				
35) The device has a device-specific guidance document, special controls document, and/ or requirements in a device-specific regulation regarding performance data that is applicable to the subject device.			X		
36) If literature is referenced in the submission, submission includes:			X		
37) For each completed animal study, the submission provides the following:					
a) Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120.	X				
b) Submission includes final study report which includes all elements outlined in 21 CFR 58.185.	X				
c) Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	X				
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)					

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

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
is an in vitro diagnostic device.					
☒ is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

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

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

Decision: (•) Accept ( ) Refuse to Accept

If Accept, notify applicant.

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

Digital Signature Concurrence Table	
Reviewer Sign-Off	Mehmet A. Kosoglu -A 2016.03.29 15:12:32 -04'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

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

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(b) (4) Proposed Labeling

(b) (4) Proposed Labeling

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(b) (4) Proposed Labeling

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(b) (4) Proposed Labeling

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 9, 2016

K160752
Ethicon Endo-Suregery, LLC
Device Trade Name: Harmonic HD 1000i Shears 20 cm Length,
Harmonic HD 1000i Shears 36 cm Length
Contact Name: David Locke

DEFICIENCY LIST

Indications for use

1. (b) (4) Deficiency Letter [redacted]

Performance Testing:

2. (b) (4) Deficiency Letter [redacted]

3. [redacted]

Cleaning, Disinfection, Sterilization, Shelf-Life and Reuse

4. (b) (4) Deficiency Letter [redacted]

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Electrical Safety and EMC

5. (b) (4) Deficiency Letter [redacted]

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Contact History

Digital Signature Concurrence Table	
Reviewer Sign-Off	

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

May 9, 2016</br></br> We have reviewed your submission K160752 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K160752 to:

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

Please refer to the eCopy guidance at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf for current information on the number of copies and the format (paper versus eCopy) you must submit.

Your response is due within 180 days from the date of this request, which is November 5, 2016. If a complete response is not received in CDRH's Document Control Center within 180 days, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

Should you have questions about this email, you may contact Mehmet Kosoglu, the lead reviewer assigned to your submission.

 *** This is a system-generated email notification ***

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

March 30, 2016</br></br>
Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K160752, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Mehmet Kosoglu.

 *** This is a system-generated email notification ***

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

(b) (4) Proposed Labeling

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Date: 4/27/2016

From: Christopher K. Dugard, M.S.
Biologist
CDRH/ODE/DAGRID/INCB

Through: Elizabeth Claverie, M.S. (Branch Chief)
CDRH/ODE/DAGRID/INCB

To: Mehmet Kosoglu
CDRH/ODE/DSD/GSDB-2

Subject: CON167518 – Sterility Review
K160752; Ethicon Endo-Surgery, LLC – Harmonic HD 1000i Shears

---

Summary:

Please note that all comments are taken/summarized from the sponsor's submission, unless noted as a "**Reviewer comment**".

Summary of issues:

- (b) (4) [redacted]
- [redacted]

Please see **Recommended Deficiencies** for more information.

Background:

Device Description:

The HARMONIC HD 1000i Shears are a sterile, single patient use device used for dissection, grasping, coagulation, and cutting between the blade and clamp arm. It consists of an ergonomic grip housing assembly with two hand control buttons: 1) Energy button for power levels 1-5 and, 2) Energy with Advanced Hemostasis button for large vessel sealing. The device is available in two shaft lengths, 20 cm and 36 cm, and both device shafts can be rotated continuously to facilitate visualization and access to targeted tissue.

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

An integrated audible and tactile mechanism in the grip housing indicates full trigger closure. The device has a clamp arm and coated curved blade that is designed to work through a 5 mm trocar, through a 5 mm reducer cap in a larger diameter trocar, or through an incision without theuse of a trocar. The blade used in the HARMONIC HD 1000i Shears has a slightly different blade design than that of the predicate device, the HARMONIC ACE+ Shears with Advanced Hemostasis (cleared under K132612 on October 17, 2013), and is also slightly longer and more tapered than the predicate device. Additionally, two dashes have been added to the device which are intended to represent relative vessel size.

The distal/front Energy button is indicated for vessels up to 5 mm in diameter. The Energy with Advanced Hemostasis button (the Green button), which is found on the side of the device handle, is designed for larger vessels and is indicated for vessels up to 7 mm in diameter. The device utilizes Adaptive Tissue Technology (the technological characteristics of which were first cleared under K120729 on May 17, 2012). This technology provides the generator with the ability to identify and monitor the instrument during use.

The HARMONIC HD 1000i Shears are designed for use exclusively with the Ethicon Generator 11 (GEN11).

Indications for Use:

The Harmonic HD 1000i Shears instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, energy-aided dissection, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis.

I was asked to review the following:

Please review the EtO sterilization method and validation.

Review:

Sterility:

(b) (4)

[redacted]

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

(b) (4)

[redacted]

(b) (4)

[redacted]

Shelf-Life/Packaging:

(b) (4)

[redacted]

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

(b) (4)

[redacted]

Recommended Deficiencies:

(b) (4)

[redacted]

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

(b) (4)



http://www.fda.gov/downloads/MedicalDevices/.../ucm109897.pdf

- You provided a summary of the tests you intend to perform to validate the sterility of your device. While the proposed tests are appropriate, you did not include pyrogen testing. Since the subject device will be used in various surgical procedures and will be in contact with blood, we recommend including pyrogen testing. Please submit a summary of this testing in addition to other proposed sterility validation tests. Otherwise, you may justify why pyrogen testing is not needed. This will help mitigate the risk of a febrile reaction and ensure the safe use of the device.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Christopher K. Dugard -S (Affiliate) 2016.04.27 16:42:14 -04'00'
Branch Chief Sign-Off	Clarence W. Murray Iii III -S Digitally signed by Clarence W. Murray Iii III -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300197254, cn=Clarence W. Murray Iii III -S Date: 2016.05.09 11:01:55 -04'00'

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

ENGINEERING CONSULTATION MEMO

MEMO TO THE RECORD
K160752

DATE: April 29, 2016 **OFFICE:** ODE

TO: Mehmet Kosoglu, Ph.D. / Lead Reviewer

FROM: Mykhaylo Nosovskyy, Ph.D. **DIVISION:** DSD/GSDB2

Cc: Long Chen, Ph.D. / Branch Chief, GSDB 2

DEVICE NAME: Harmonic HD 1000i Shears

SPONSOR: Ethicon Endo-Surgery, LLC

RECOMMENDATION: AI request

SUMMARY:

The purpose of this submission is to introduce to the market '*FTRD System Set*'. I was requested to perform review of the Marking Probe.

I reviewed following sections:

- Section 4: IFU Statement
- Section 11: Device Description
- Section 12: SE Discussion
- Section 13: Proposed Labeling
- Section 18: Performance Testing - Bench
- Section 19: Performance Testing - Animal

Identified deficiencies are listed at the end of this consult memo.

INDICATIONS FOR USE:

(b) (4)

[redacted]

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Reviewer Comments:

The sponsor intended use "energy-aided dissection" as in IFU of subject device

DEVICE DESCRIPTION

The HARMONIC HD® 1000i Shears are sterile, single patient use device used for dissection, grasping, coagulation, and cutting between the blade and clamp arm (see Figure 10-1). It consists of an ergonomic grip housing assembly with two hand control buttons: 1) Energy button for power levels 1-5 and, 2) Energy with Advanced Hemostasis button for large vessel sealing. The device is available in two shaft lengths, 20 cm and 36 cm, and both device shafts can be rotated continuously to facilitate visualization and access to targeted tissue.

An integrated audible and tactile mechanism in the grip housing indicates full trigger closure. The device has a clamp arm and coated curved blade that is designed to work through a 5 mm trocar, through a 5 mm reducer cap in a larger diameter trocar, or through an incision without the use of a trocar. The blade used in the HARMONIC® HD 1000i Shears have a slightly different blade design than that of the predicate device, the HARMONIC® ACE+ Shears with Advanced Hemostasis (cleared under K132612 on 17 Oct 2013) and is also slightly longer than the predicate device. The two dashes on the device are intended to represent relative vessel size.

(b) (4)

[redacted]

(b) (4)

[redacted]

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

(b) (4)

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

(b) (4) Test Data

[redacted]

LABELING

(b) (4) Test Data

[redacted]

PERFORMANCE TESTING

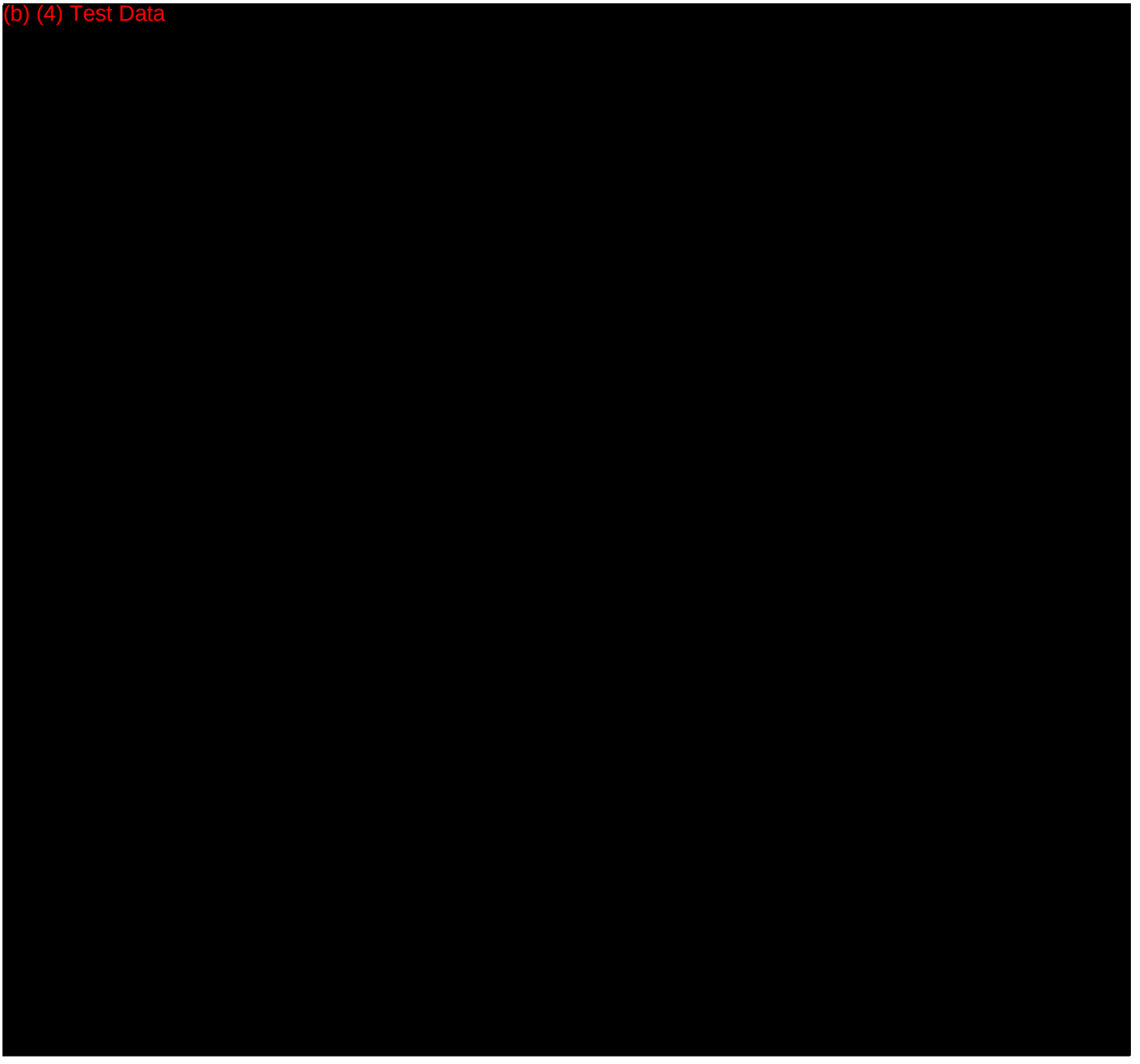
(b) (4) Test Data

[redacted]

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

(b) (4) Test Data



Acute Animal Testing

(b) (4) Test Data



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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Survival Animal Testing

(b) (4) Test Data

[redacted]

Testing Results:

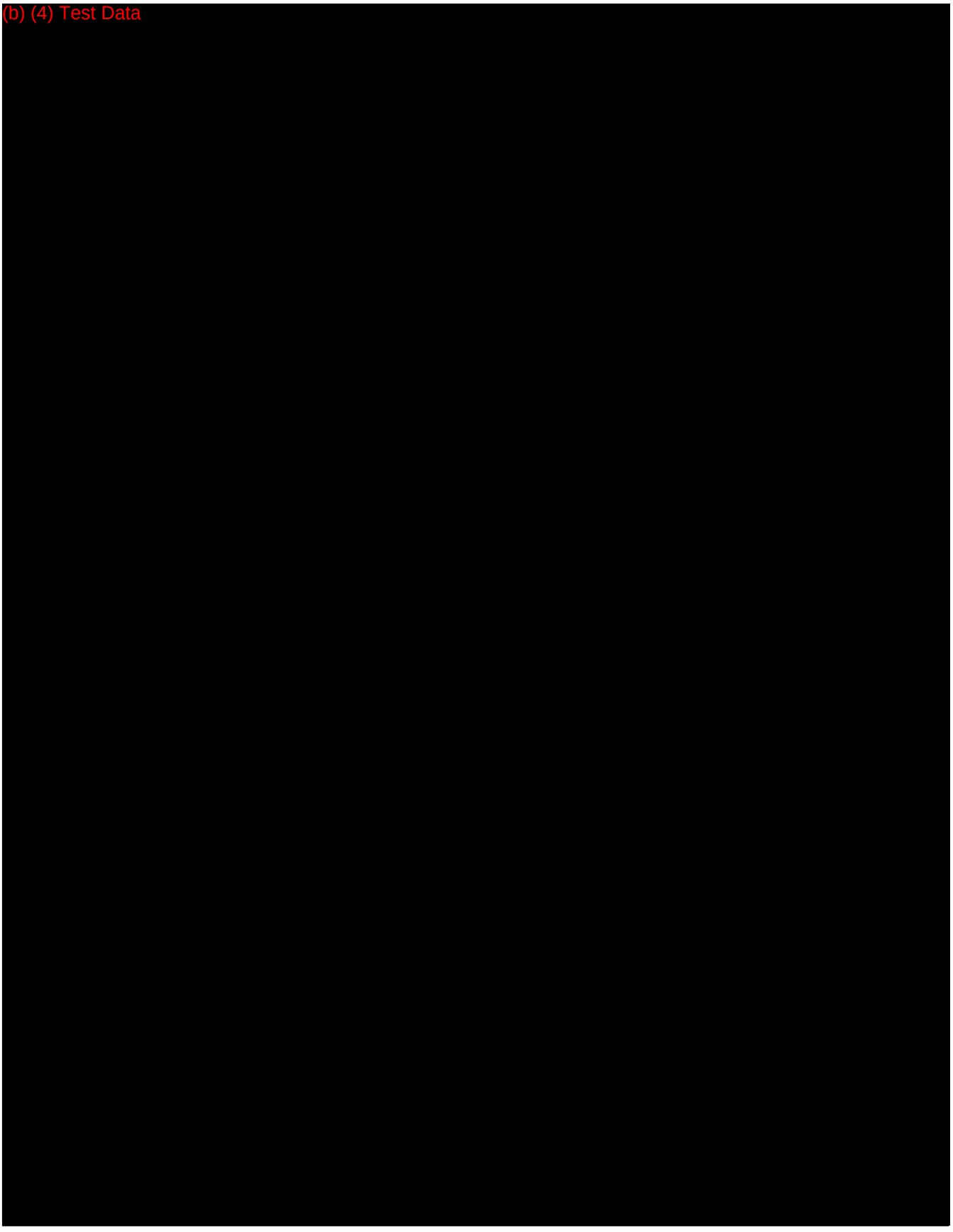
(b) (4) Test Data

[redacted]

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

(b) (4) Test Data



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

(b) (4) Test Data

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
CDRH/ODE/DSD/GSDB1
WO66 RM1567
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6194

Premarket Notification 510(k) Review

Post-Review Reminders

- ☐ Final Check: Ensure your documentation accurately reflects the final recommendation prior to signature (e.g., Review Summary, data in the Device Description section, the Labeling section, etc)
- ☐ Complete CTS: Procode, Clinical Trials, Combo Product, MR compatibility
- ☐ Ensure the content of the 510(k) Summary is accurate (N/A if a 510(k) Statement was provided instead).
- ☐ For SE Decisions: Upload SE Letter, and PDFs of IFU form and 510(k) Summary (if included) in DocMan.

To add reminders, type the reminder in the text field to the left then press the Tab key.

Date: May 9, 2016

Reviewer: Mehmet Kosoglu

Subject: Traditional 510(k)# K160752

Applicant: Ethicon Endo-suregery, LLC	**Device Trade Name:** Harmonic Hd 1000i Shears 20 Cm Length, Harmonic Hd 1000i Shears 36 Cm Length
Contact Name: David Locke	**Contact Title:** Senior Regulatory Affairs Specialist
Correspondent Firm: Ethicon Endo-surgery, LLC	**Phone:** (513) 337-1281 **Email:** dlocke1@its.jnj.com
Received Date: March 18, 2016	**Due Date:** June 16, 2016
Pro Code(s): LFL **Class:** Unclassified **Reg #:**	**Reg Name:**

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K132612	LFL	Harmonic Ace+ Shears 23 Cm Length With Advanced Hemostasis, Harmonic Ace + Laparoscopic Shears 36 Cm Length With Advance	Ethicon Endo-surgery, LLC

Review Summary

Recommendation

I recommend that the Harmonic Hd 1000i Shears 20 Cm Length, Harmonic Hd 1000i Shears 36 Cm Length is/are in need of Additional Information (AINN)

Review Team

Lead Reviewer — Mehmet Kosoglu (CDRH/ODE/DSD/GSDB1)

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

I. Purpose and History

I was not able to identify any MDR reports for Harmonic Shears.

II. 510(k) Summary/Statement

510(k) Summary/Statement		
Was a 510(k) Summary or Statement provided?	Summary	Undo
The 510(k) Summary is complete.		

Reviewer Recommendation
The 510(k) Summary/Statement is acceptable.

III. Device/System Description

Device Characteristics		Inadequate Or Marked
Is the intended use or fundamental technology new?	No	☐
Is the device life-supporting or life sustaining?	No	☐
Are there any direct or indirect patient contacting components?	Yes	☐
• Is the device or a component an implant?	No	☐
Does the device use software/firmware?	No	☐
Does the device or a component need sterilization (by manufacturer or user)?	Yes	☐
The device/system uses or is…	a single use device(s) (SUD)	☐
The environment for use of the device/system includes…	Hospital	☐
Is the device a combination product?	N - Not a Part 3 Combination Product	☐
Is the device/system electrical (battery or wall powered)?	Yes, it is mains powered Only	☐

Check the attributes that are applicable to this submission.

	Nanotechnology	Reprocessed SUD	Companion Diagnostic	Medical Counter Measures
Yes	☐	☐	☐	☐
No	☒	☒	☒	☒
Unknown	☐	☐	☐	☐

Device Description Table: Summary of important device characteristics

The device, The HARMONIC HD 1000i Shears are a sterile, single patient use device used for dissection, grasping, coagulation, and cutting between the blade and clamp arm. It consists of an ergonomic grip housing assembly with two hand control buttons: 1) Energy button for power levels 1-5 and, 2) Energy with Advanced Hemostasis button for large vessel sealing. The device is available in two shaft lengths, 20 cm and 36 cm, and both device shafts can be rotated continuously to facilitate visualization and access to targeted tissue. An integrated audible and tactile

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

(b) (4)

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Reviewer Recommendation
The Device Description is acceptable.

IV. Comparison of Indications for Use to Predicate Devices

Comparison of Indications for Use

Subject

510(k) #: K160752 Rx/OTC:

Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/ Newborn
Yes	☐	☐	☐	☐	☐	☐	☐	☐
No	☐	☐	☐	☐	☐	☐	☐	☐
Unknown	☒	☒	☒	☒	☒	☒	☒	☒

Indications for Use: The Harmonic HD 1000i Shears instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, energy-aided dissection, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis.

Predicate(s)

Submission#: K132612 Rx/OTC: Rx

Intended Population:

Indications for Use: The harmonic ace®+ shears with advanced hemostasis are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter using the advanced hemostasis hand control button.

Indications for Use Table: Compares the indications for use of the subject and predicate devices.

Reviewer Recommendation

(b) (4) [redacted]

V. Comparison of Technology to Predicate Devices

(b) (4) [redacted]

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

(b) (4)

[redacted]

(b) (4)

[redacted]

VI. Labeling

Labeling Review Needed?	Yes	Undo
Usability Consult Needed?	Undo	No

A General Labeling Requirements

General Labeling Requirements		Inadequate or Marked
Is the prescription statement (or "Rx only") included?	Yes	☐
Adequate instructions for OTC use?	Inapplicable	☐
The indications for use are consistent with the IFU page?	Yes	☐
Appropriate contraindications, warnings, precautions and adverse events provided?	Yes	☐
Instructions are in accordance with the guidance (if applicable)?	Yes	☐
Appropriate labeling inside device?	Yes	☐
Appropriate label/indicator outside device?	Yes	☐
Appropriate Manual labeling?	Yes	☐
What MRI safety information does the labeling contain?	Not Evaluated and Not Needed	☐

Labeling Table: A summary of the adequacy of several labeling requirements.

Reviewer Recommendation

(b) (4)

[redacted]

VII. Reprocessing, Sterilization, and Shelf-Life

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

(b) (4)

(b) (4)

(b) (4)

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

XVI. Original Deficiencies

Indications for use

1. (b) (4) [redacted]

Performance Testing:

2. (b) (4) [redacted]

3. [redacted]

Cleaning, Disinfection, Sterilization, Shelf-Life and Reuse

4. (b) (4) [redacted]

Electrical Safety and EMC

5. (b) (4) [redacted]

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

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

XVII. Contact History

Digital Signature Concurrence Table	
Reviewer Sign-Off	Mehmet A. Kosoglu -A 2016.05.09 10:21:04 -04'00'

Long H. Chen -A

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=1300369056
Date: 2016.05.09 10:31:57 -04'00'

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

ENGINEERING CONSULTATION MEMO

MEMO TO THE RECORD
K160752/S001

DATE: June 13, 2016 **OFFICE:** ODE

TO: Mehmet Kosoglu, Ph.D. / Lead Reviewer

FROM: Mykhaylo Nosovskyy, Ph.D. **DIVISION:** DSD/GSDB2

Cc: Long Chen, Ph.D. / Branch Chief, GSDB 2

DEVICE NAME: Harmonic HD 1000i Shears

SPONSOR: Ethicon Endo-Surgery, LLC

RECOMMENDATION: All deficiencies addressed adequately.

SUMMARY:

The purpose of this submission is to introduce to the market '*Harmonic HD 1000i Shears*'. I was requested to perform review of the performance testing.

I reviewed following sections:

- Section 4: IFU Statement
- Section 11: Device Description
- Section 12: SE Discussion
- Section 13: Proposed Labeling
- Section 18: Performance Testing - Bench
- Section 19: Performance Testing - Animal

After review of original submission, I identified two deficiencies which are are listed at the end of this consult memo. In Supplement 001 the sponsor adequately addressed all deficiencies.

INDICATIONS FOR USE:

(b) (4)

[redacted]

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Reviewer Comments:

The sponsor introduced "energy-aided dissection" in to IFU of subject device.

In Supplement 001 the sponsor revised sugar coated IFU to exclude "energy-aided dissection"

DEVICE DESCRIPTION

The HARMONIC HD® 1000i Shears are sterile, single patient use device used for dissection, grasping, coagulation, and cutting between the blade and clamp arm (see Figure 10-1). It consists of an ergonomic grip housing assembly with two hand control buttons: 1) Energy button for power levels 1-5 and, 2) Energy with Advanced Hemostasis button for large vessel sealing. The device is available in two shaft lengths, 20 cm and 36 cm, and both device shafts can be rotated continuously to facilitate visualization and access to targeted tissue.

An integrated audible and tactile mechanism in the grip housing indicates full trigger closure. The device has a clamp arm and coated curved blade that is designed to work through a 5 mm trocar, through a 5 mm reducer cap in a larger diameter trocar, or through an incision without the use of a trocar. The blade used in the HARMONIC® HD 1000i Shears have a slightly different blade design than that of the predicate device, the HARMONIC® ACE+ Shears with Advanced Hemostasis (cleared under K132612 on 17 Oct 2013) and is also slightly longer than the predicate device. The two dashes on the device are intended to represent relative vessel size.

(b) (4)

[redacted]

(b) (4)

[redacted]

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

(b) (4)

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

(b) (4)

[redacted]

LABELING

(b) (4)

[redacted]

PERFORMANCE TESTING

(b) (4)

[redacted]

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

(b) (4)

[redacted]

Acute Animal Testing

(b) (4)

[redacted]

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

(b) (4)

[redacted]

Survival Animal Testing

(b) (4)

[redacted]

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

(b) (4)

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

(b) (4)

[redacted]

DEFICIENCIES

Performance Testing:

(b) (4)

[redacted]

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

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

RECOMMENDATION

All deficiencies addressed adequately.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Mykhaylo B. Nosovskyy -S 2016.06.13 20:19:54 -04'00'
Branch Chief Sign-Off	

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Date: 6/10/2016

From: Christopher K. Dugard, M.S.
Biologist
CDRH/ODE/DAGRID/INCB

Through: Elizabeth Claverie, M.S. (Branch Chief)
CDRH/ODE/DAGRID/INCB

To: Mehmet Kosoglu
CDRH/ODE/DSD/GSDB-2

Subject: CON1611350 – Sterility Review
K160752/S001; Ethicon Endo-Surgery, LLC – Harmonic HD 1000i Shears

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Summary:

This is a follow up consult for CON167518.

Please note that all comments are taken/summarized from the sponsor's submission, unless noted as a **"Reviewer comment"**.

The following issues were noted in the original consult:

- (b) (4)
- [redacted]

The lead reviewer elected not to request pyrogen testing based on the limited contact duration and the regulatory background of the device.

Following submission of the sponsor's response to the request for additional information and interactive review, the sponsor has addressed all concerns in regards to sterility/shelf-life.

Background:

Device Description:

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

The HARMONIC HD 1000i Shears are a sterile, single patient use device used for dissection, grasping, coagulation, and cutting between the blade and clamp arm. It consists of an ergonomic grip housing assembly with two hand control buttons: 1) Energy button for power levels 1-5 and, 2) Energy with Advanced Hemostasis button for large vessel sealing. The device is available in two shaft lengths, 20 cm and 36 cm, and both device shafts can be rotated continuously to facilitate visualization and access to targeted tissue.

An integrated audible and tactile mechanism in the grip housing indicates full trigger closure. The device has a clamp arm and coated curved blade that is designed to work through a 5 mm trocar, through a 5 mm reducer cap in a larger diameter trocar, or through an incision without theuse of a trocar. The blade used in the HARMONIC HD 1000i Shears has a slightly different blade design than that of the predicate device, the HARMONIC ACE+ Shears with Advanced Hemostasis (cleared under K132612 on October 17, 2013), and is also slightly longer and more tapered than the predicate device. Additionally, two dashes have been added to the device which are intended to represent relative vessel size.

The distal/front Energy button is indicated for vessels up to 5 mm in diameter. The Energy with Advanced Hemostasis button (the Green button), which is found on the side of the device handle, is designed for larger vessels and is indicated for vessels up to 7 mm in diameter. The device utilizes Adaptive Tissue Technology (the technological characteristics of which were first cleared under K120729 on May 17, 2012). This technology provides the generator with the ability to identify and monitor the instrument during use.

The HARMONIC HD 1000i Shears are designed for use exclusively with the Ethicon Generator 11 (GEN11).

Indications for Use:

The Harmonic HD 1000i Shears instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, energy-aided dissection, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis.

I was asked to review the following:

Please review the EtO sterilization method and validation.

Review:

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

(b) (4)

(b) (4)

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Digital Signature Concurrence Table	
Reviewer Sign-Off	Christopher K. Dugard -S (Affiliate) 2016.06.10 09:36:57 -04'00'
Branch Chief Sign-Off	

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
CDRH/ODE/DSD/GSDB1
WO66 RM1567
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6194

Premarket Notification 510(k) Review

Date: June 28, 2016

Reviewer: Mehmet Kosoglu

Subject: Traditional 510(k)# K160752/S001

Applicant: Ethicon Endo-suregery, LLC	**Device Trade Name:** Harmonic Hd 1000i Shears 20 Cm Length, Harmonic Hd 1000i Shears 36 Cm Length
Contact Name: David Locke	**Contact Title:** Senior Regulatory Affairs Specialist
Correspondent Firm: Ethicon Endo-surgery, LLC	**Phone:** (513) 337-1281 **Email:** dlocke1@its.jnj.com
Received Date: May 23, 2016	**Due Date:** June 30, 2016
Pro Code(s): LFL **Class:** Unclassified **Reg #:**	**Reg Name:**

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K132612	LFL	Harmonic Ace+ Shears 23 Cm Length With Advanced Hemostasis, Harmonic Ace + Laparoscopic Shears 36 Cm Length With Advance	Ethicon Endo-surgery, LLC

Review Summary

The proposed device uses ultrasonic vibrations to cut and coagulate tissue and seal blood vessels. The technology of the proposed device is very similar to the predicate. The sponsor provided bench and animal testing to show that the proposed device can cut and seal blood vessels with a similar performance compared to the predicate.

Recommendation

I recommend that the Harmonic Hd 1000i Shears 20 Cm Length, Harmonic Hd 1000i Shears 36 Cm Length is/are Substantially Equivalent (SESE)

Review Team

Lead Reviewer Mehmet Kosoglu (CDRH/ODE/DSD/GSDB1)

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

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

I. Purpose and History

I was not able to identify any MDR reports for Harmonic Shears.

II. 510(k) Summary/Statement

510(k) Summary/Statement		
Was a 510(k) Summary or Statement provided?	Summary	Undo
The 510(k) Summary is complete.		

Reviewer Recommendation
The 510(k) Summary/Statement is acceptable.

III. Device/System Description

Device Characteristics		Inadequate Or Marked
Is the intended use or fundamental technology new?	No	☐
Is the device life-supporting or life sustaining?	No	☐
Are there any direct or indirect patient contacting components?	Yes	☐
• Is the device or a component an implant?	No	☐
Does the device use software/firmware?	No	☐
Does the device or a component need sterilization (by manufacturer or user)?	Yes	☐
The device/system uses or is...	a single use device(s) (SUD)	☐
The environment for use of the device/system includes...	Hospital	☐
Is the device a combination product?	N - Not a Part 3 Combination Product	☐
Is the device/system electrical (battery or wall powered)?	Yes, it is mains powered Only	☐

Check the attributes that are applicable to this submission.

	Nanotechnology	Reprocessed SUD	Companion Diagnostic	Medical Counter Measures
Yes	☐	☐	☐	☐
No	☒	☒	☒	☒
Unknown	☐	☐	☐	☐

Device Description Table: Summary of important device characteristics

The device, The HARMONIC HD 1000i Shears are a sterile, single patient use device used for dissection, grasping, coagulation, and cutting between the blade and clamp arm. It consists of an ergonomic grip housing assembly with two hand control buttons: 1) Energy button for power levels 1-5 and, 2) Energy with Advanced Hemostasis button for large vessel sealing. The device is available in two shaft lengths, 20 cm and 36 cm, and both device shafts can be rotated continuously to facilitate visualization and access to targeted tissue. An integrated audible and tactile

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

(b) (4)

Records processed under FOIA Request 2016-8748; Released by CDRH on 9/13/2018/2018

Reviewer Recommendation
The Device Description is acceptable.

IV. Comparison of Indications for Use to Predicate Devices

Comparison of Indications for Use

Subject

510(k) #: K160752 Rx/OTC:

Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/ Newborn
Yes	☐	☐	☐	☐	☐	☐	☐	☐
No	☐	☐	☐	☐	☐	☐	☐	☐
Unknown	☒	☒	☒	☒	☒	☒	☒	☒

Indications for Use: The Harmonic HD 1000i Shears instrument is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Energy button with Advanced Hemostasis.

Predicate(s)

Submission#: K132612 Rx/OTC: Rx

Intended Population:

Indications for Use: The harmonic ace®+ shears with advanced hemostasis are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers and steel scalpels in general, plastic, pediatric, gynecologic, urologic, thoracic, exposure to orthopedic structures (such as spine and joint space), sealing and transection of lymphatic vessels, and other open and endoscopic procedures. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter using the advanced hemostasis hand control button.

Indications for Use Table: Compares the indications for use of the subject and predicate devices.

Reviewer Recommendation

(b) (4) [redacted]

V. Comparison of Technology to Predicate Devices

(b) (4) [redacted]

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

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(b) (4)

[redacted]

Reviewer Recommendation

(b) (4)

[redacted]

VI. Labeling

Labeling Review Needed?	Yes	Undo
Usability Consult Needed?	Undo	No

A General Labeling Requirements

General Labeling Requirements		Inadequate or Marked
Is the prescription statement (or "Rx only") included?	Yes	☐
Adequate instructions for OTC use?	Inapplicable	☐
The indications for use are consistent with the IFU page?	Yes	☐
Appropriate contraindications, warnings, precautions and adverse events provided?	Yes	☐
Instructions are in accordance with the guidance (if applicable)?	Yes	☐
Appropriate labeling inside device?	Yes	☐
Appropriate label/indicator outside device?	Yes	☐
Appropriate Manual labeling?	Yes	☐
What MRI safety information does the labeling contain?	Not Evaluated and Not Needed	☐

Labeling Table: A summary of the adequacy of several labeling requirements.

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

(b) (4)

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(b) (4)

[redacted]

XI. Performance Testing

A (b) (4)

[redacted]

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

(b) (4)

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Is the predicate device legally marketed?	☒	☐
Do the devices have the same intended use?	☒	☐
Please explain how the intended use of the subject device is similar to or different from the predicate device: Indications for use are identical.		
Do the devices have the same technological characteristics?	☐	☒
Please describe the different technological characteristics: The new device uses different power, voltage, speed, and has a different shaft length.		
Do the different technological characteristics of the devices raise different questions of safety and effectiveness?	☐	☒
Are the methods acceptable?	☒	☐
Do the data demonstrate equivalence and support the Indications for Use?	☒	☐
Please explain how the data do or do not demonstrate substantial equivalence: Burst pressure testing with the sealed vessels show that proposed device is as effective as the predicate in terms of dissecting and sealing vessels.		

XVI. Original Deficiencies

Indications for use

1. (b) (4) [redacted]

(b) (4) [redacted]

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

(b) (4)

(b) (4)

(b) (4)

(b) (4)