

Section 6**510(k) Summary**

JUN 11 2013

6. 510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT: Sonendo, Inc.
DATE PREPARED: December 29, 2012
CONTACT PERSON: Dan W. Miller
 Sonendo, Inc.
 26061 Merit Circle, Suite 101
 Laguna Hills, CA 92653
 Phone: (949) 766.3636 x 544
TRADE NAME: Sonendo Endotherapy System
COMMON NAME: Sonic Cleaning and Irrigation System
CLASSIFICATION NAME: Ultrasonic Scaler
DEVICE CLASSIFICATION: Class 2, per 21 CFR 872.4850
PRODUCT CODE ELC
PREDICATE DEVICES: EMS Piezon Master 700 (K093000)
 Sonic Air MM 1500+.(MID) (K081268)

Substantially Equivalent To:

The Sonendo Endotherapy System is substantially equivalent in intended use, principal of operation and technological characteristics to the EMS Piezon Master 700 (K093000) and the Sonic Air MM 1500+ (MID) (K081268).

Description of the Device Subject to Premarket Notification:

The Sonendo Endotherapy System is a medical device intended to prepare, clean and irrigate root canals. The Sonendo Endotherapy System is comprised of a Console, Foot Pedal and Molar Procedure Kit with a Handpiece.

Indication for Use:

The Sonendo Endotherapy System is intended to prepare, clean and irrigate 1st and 2nd molar teeth indicated for root canal therapy.

Technical Characteristics:

The Sonendo Endotherapy System has similar physical and technical characteristics to the predicate devices. These characteristics are tabulated below:

Sonendo, Inc.
 Sonendo Endotherapy System

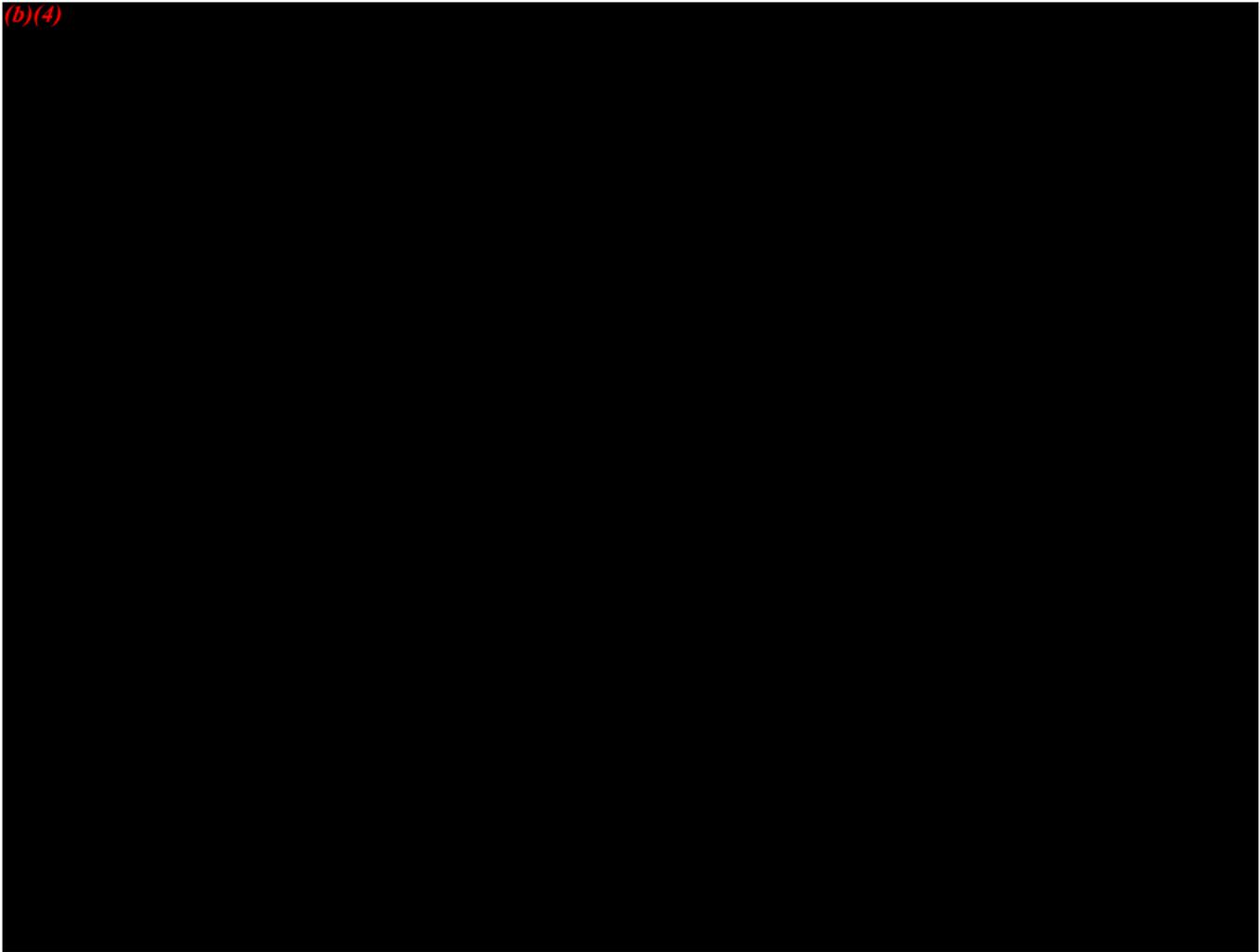
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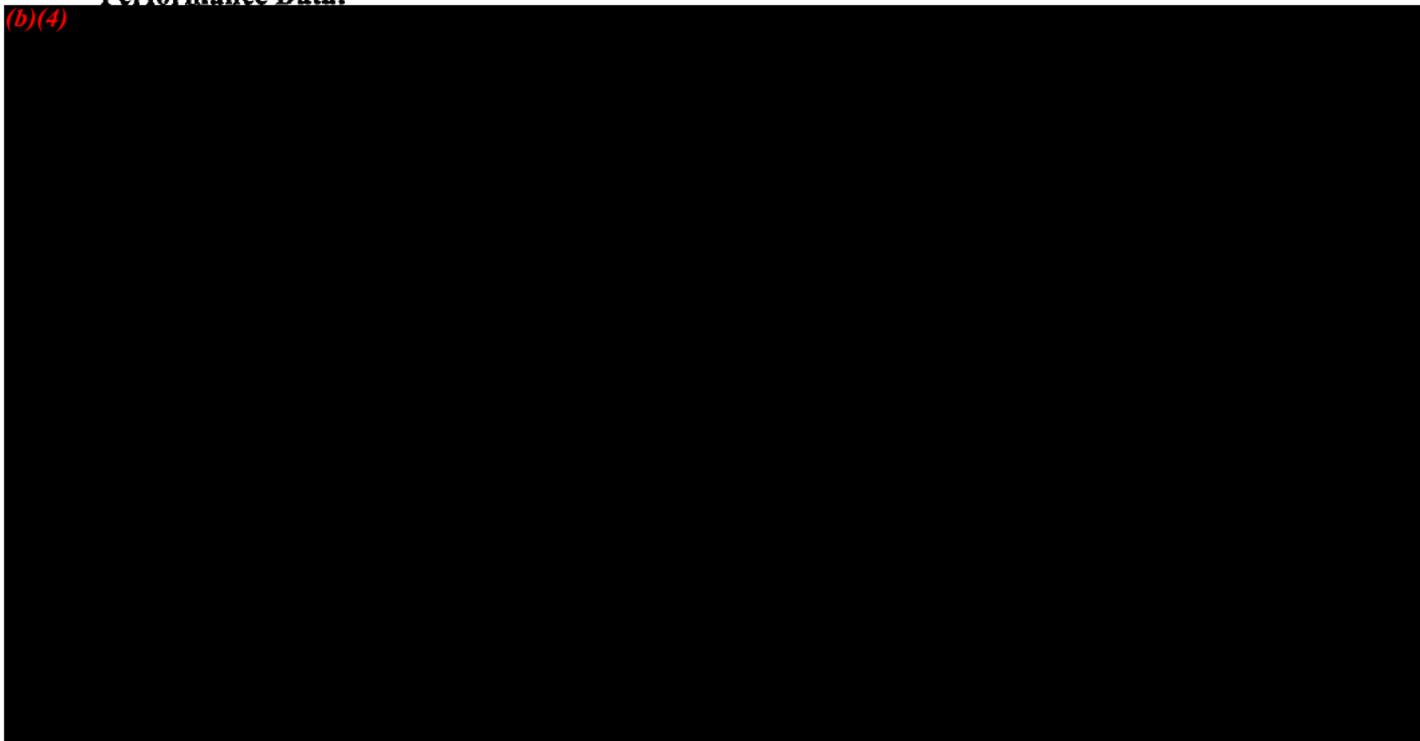
510(k) Summary

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Performance Data:

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Section 6

510(k) Summary

Basis for Determination of Substantial Equivalence:

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Sonendo Endotherapy System is determined by Sonendo, Inc., to be substantially equivalent to existing legally marketed devices.



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 11, 2013

Mr. Dan W. Miller
Sonendo, Incorporated
26061 Merit Circle, Suite 101
LAGUNA HILLS CA 92653

Re: K130025
Trade/Device Name: Sonendo Endotherapy System
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: May 7, 2013
Received: May 16, 2013

Dear Mr. Miller:

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.

Page 2 – Mr. Miller

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.

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

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

Sincerely yours,

Susan Runner  *Mary S. Runner -S*

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5

Indications for Use Statement

5. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130025

Device Name: **Sonendo Endotherapy System**

Indications for Use:

The Sonendo Endotherapy System is intended to prepare, clean and irrigate 1st and 2nd molar teeth indicated for root canal therapy.

AND/OR

Prescription Use X
(Part 21 CFR 801 Subpart D)

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen
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Page of

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K130025



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

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Sincerely yours,

  **Mary S. Runner -S**

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Traditional 510(k) PREMARKET NOTIFICATION
Sonendo Endotherapy System

APPLICANT

Sonendo, Inc.
26061 Merit Circle, Suite 101
Laguna Hills, CA 92653

OFFICIAL CORRESPONDENT

Dan W. Miller
Phone: 949.766.3636 x 544
FAX: 949.348.1866

(b)(4)

**SONENDO ENDOTHERAPY SYSTEM
TRADITIONAL 510(K) PREMARKET NOTIFICATION**

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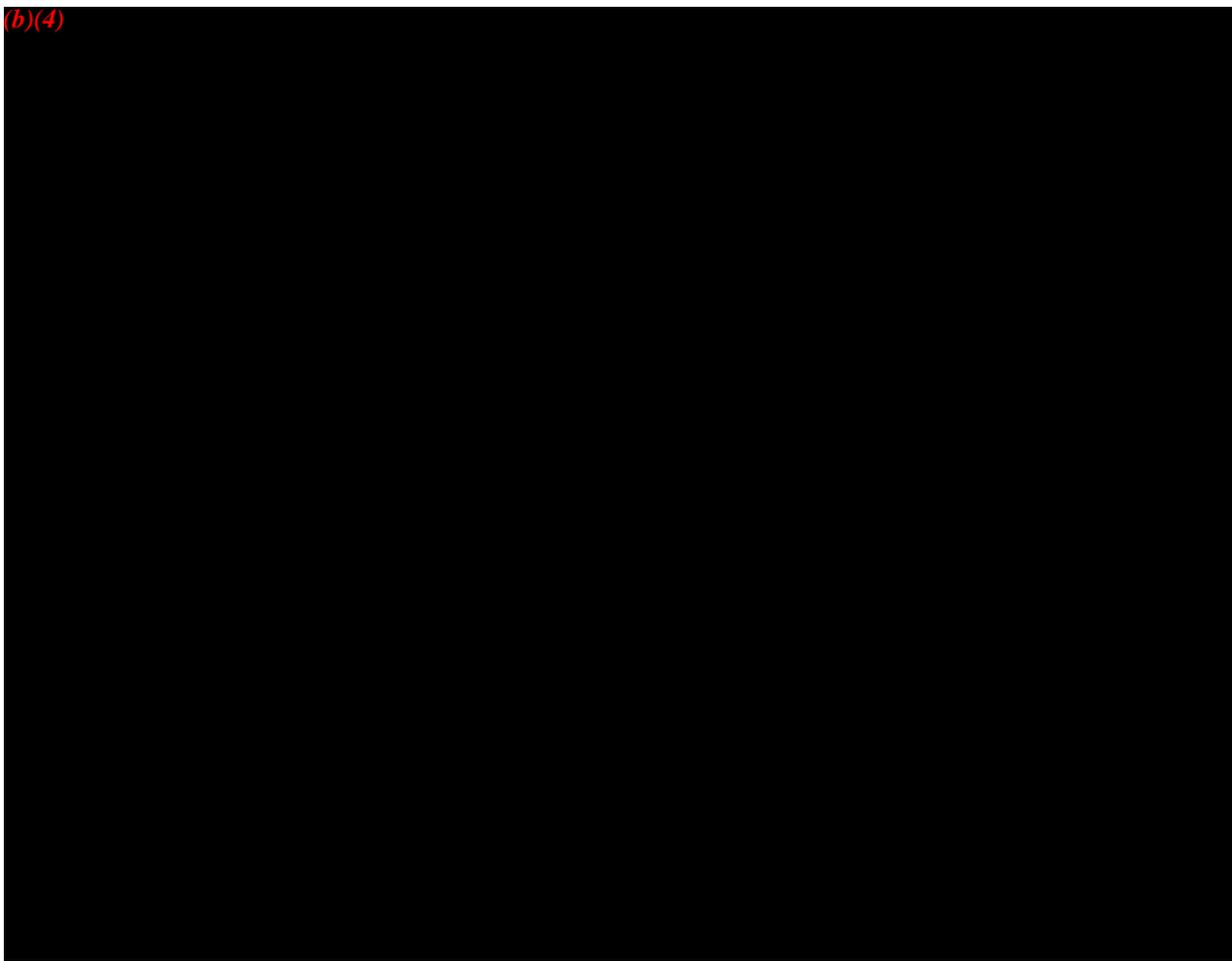
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APPENDICES

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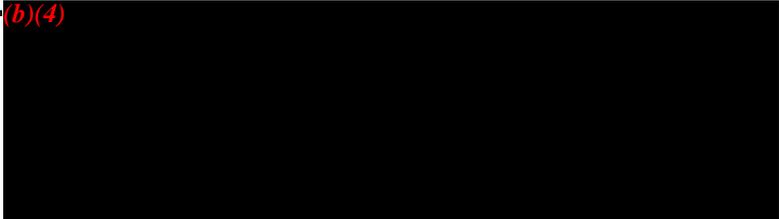
Section 1

Medical Device User Fee cover Sheet

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

(see attached)

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



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)

SONENDO INC
Sonendo, Inc.
26061 Merit Circle
Suite 101
26061 Merit Circle
Laguna Hills CA 92653
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****1718

2. CONTACT NAME

Dan Miller

2.1 E-MAIL ADDRESS



2.2 TELEPHONE NUMBER (include Area code)

949-766-3636

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

949-305-5201

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

Select an application type:

3.1 Select a center

- 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)
- Annual Fee for Periodic Reporting (APR)
- 30-Day Notice

- CDRH
- CBER

3.2 Select one of the types below

Original Application

Supplement Types:

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

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

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

NO, I am not a small business

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

Section 2 **Certification of Compliance- ClinicalTrials.gov**

- 2. Certification of Compliance with ClinicalTrials.gov FDA Form 3674**
(see attached)



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 Sonendo, Inc.	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES December 2012
3. ADDRESS (Number, Street, State, and ZIP Code) 26061 Merit Circle, Suite 101 Laguna Hills, CA 92653	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 949.766.3636 (Fax) 949.348.1866

PRODUCT INFORMATION

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

Ultrasonic Scaler, ELC, Class 2

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)
 N/A

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

CERTIFICATION STATEMENT / INFORMATION

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

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

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

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

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

NCT Number(s): _____

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

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Dan W. Miller (Title) Vice President of Regulatory Affairs, Clinical Affairs, & Qual
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) 26061 Merit Circle, Suite 101 Laguna Hills, CA 92653	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 949.766.3636 x 544 (Fax) 949.348.1866
15. DATE OF CERTIFICATION 12/29/12	

Instructions for Completion of Form FDA 3674**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**

Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.

Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

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

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

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

Section 3

Standards Data Report Form(s)

3. Standards Data Report FDA Form 3654

(see attached)

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

ISO 10993-1 Biological Evaluation of Medical Device- Part 1 Evaluation and Testing (2009)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #02-156

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

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
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: G-95 Blue Book Memorandum: Use of ISO 10993-1

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

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

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>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-1 Biological Evaluation of Medical Device- Part 1 Evaluation and Testing (2009)

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED *
See attached description of compliance located in section 16 of this 510k submission

DESCRIPTION
See attached description of compliance located in section 16 of this 510k submission

JUSTIFICATION
See attached description of compliance located in section 16 of this 510k submission

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

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

Paperwork Reduction Act Statement

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

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-5 Biological Evaluation of Medical Device- Part 15 Tests for in vitro cytotoxicity (2009)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #2-153

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

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

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

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

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

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

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

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

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

Title of guidance: _____

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

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

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

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

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

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

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-5 Biological Evaluation of Medical Device- Part 15 Tests for in vitro cytotoxicity (2009)

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED *
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DESCRIPTION
See attached description of compliance located in section 16 of this 510k submission

JUSTIFICATION
See attached description of compliance located in section 16 of this 510k submission

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-10 Biological Evaluation of Medical Device- Part 10 Tests for irritation and delayed hypersensitivity (2002)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #2-87

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: _____

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

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-10 Biological Evaluation of Medical Device- Part 10 Tests for irritation and delayed hypersensitivity (2002)

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED *
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DESCRIPTION
See attached description of compliance located in section 16 of this 510k submission

JUSTIFICATION
See attached description of compliance located in section 16 of this 510k submission

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-11 Biological Evaluation of Medical Device- Part 11 Tests for systemic toxicity (2006)

Please answer the following questions	Yes	No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number ³	#2-118	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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 ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard?..... If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Title of guidance: _____		

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

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

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ISO 10993-11 Biological Evaluation of Medical Device- Part 11 Tests for systemic toxicity (2006)

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED *
See attached description of compliance located in section 16 of this 510k submission

DESCRIPTION
See attached description of compliance located in section 16 of this 510k submission

JUSTIFICATION
See attached description of compliance located in section 16 of this 510k submission

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 11137-1: 2006 Sterilization of Health Care Products- Radiation- Part 1 Requirements for development of validation

Please answer the following questions	Yes	No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number ³	#14-297	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of tests?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input type="checkbox"/>
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
ISO 11137-1: 2006 Sterilization of Health Care Products- Radiation- Part I Requirements for development of validation

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED *
Requirements for the development, validation and routine control of the sterilization process using VD-Max (25kGy min) method

DESCRIPTION
The validation and routine monitoring for the devices will be conducted in accordance with documented requirements

JUSTIFICATION
Unrelated methods will be omitted as a single validation method (VD Max 25 kGy) was selected

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

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

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 14-225

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

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

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

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

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

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

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

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

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

Title of guidance: _____

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

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER
All

SECTION TITLE
All

CONFORMANCE?

Yes No N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Requirements for the establishment of the sterilization dose using VD-Max (25kGy) method

DESCRIPTION

Sterilization dose will be established in accordance with documented requirements

JUSTIFICATION

Unrelated methods will be omitted as a single validation method (VD Max 25 kGy) was selected

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

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

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 60601-1-2 Edition 3:2007-03, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential perf

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #5-53

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

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

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

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

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

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

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

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

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

Title of guidance: _____

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

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

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

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

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

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>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

IEC 60601-1-2 Edition 3:2007-03, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential perf

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED *
Summary report included in Appendix 11 completely describes applied sections and the test options

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

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

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

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

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

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, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988 +Amendments

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #5-4

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>

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988 +Amendments

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED ♦

Summary report included in Appendix 12 completely describes applied sections and the test options

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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

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Paperwork Reduction Act Statement

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Department of Health and Human Services
 Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
 (To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 11607-1:2006 Packaging for Terminally Sterilized medical devices- Part I

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 14-193

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?

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Were there any exclusions from the standard?
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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
ISO 11607-1:2006 Packaging for Terminally Sterilized medical devices- Part 1

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED *
Validated test methods from Annex B incorporated into test series.

DESCRIPTION
Challenge tests included storage/transportation conditioning, microbial barrier properties, packaging-system performance testing, and stability testing.

JUSTIFICATION
Requirements for reusable containers/fabrics and impremeable material omitted as not applicable packaging design.

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

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Office of Chief Information Officer
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Rockville, MD 20850

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Section 5

Indications for Use Statement

5. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: **Sonendo Endotherapy System**

Indications for Use:

The Sonendo Endotherapy System is intended to prepare, clean and irrigate 1st and 2nd molar teeth indicated for root canal therapy.

AND/OR

Prescription Use X
(Part 21 CFR 801 Subpart D)

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page of

Section 6**510(k) Summary****6. 510(k) Summary**

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT: Sonendo, Inc.

DATE PREPARED: December 29, 2012

CONTACT PERSON: Dan W. Miller
Sonendo, Inc.
26061 Merit Circle, Suite 101
Laguna Hills, CA 92653
Phone: (949) 766.3636 x 544

TRADE NAME: Sonendo Endotherapy System

CLASSIFICATION NAME: Ultrasonic Scaler

DEVICE CLASSIFICATION: Class 2, per 21 CFR 872.4850

PRODUCT CODE ELC

PREDICATE DEVICES: EMS Piezon Master 700 (K093000)
Sonic Air MM 1500+ (MID) (K081268)

Substantially Equivalent To:

The Sonendo Endotherapy System is substantially equivalent in intended use, principal of operation and technological characteristics to the EMS Piezon Master 700 (K093000) and the Sonic Air MM 1500+ (MID) (K081268).

Description of the Device Subject to Premarket Notification:

The Sonendo Endotherapy System is a medical device intended to prepare, clean and irrigate root canals. The Sonendo Endotherapy System is comprised of a Console, Foot Pedal and Molar Procedure Kit with a Handpiece.

Indication for Use:

The Sonendo Endotherapy System is intended to prepare, clean and irrigate 1st and 2nd molar teeth indicated for root canal therapy.

Technical Characteristics:

The Sonendo Endotherapy System has similar physical and technical characteristics to the predicate devices. These characteristics are tabulated below:

Section 6

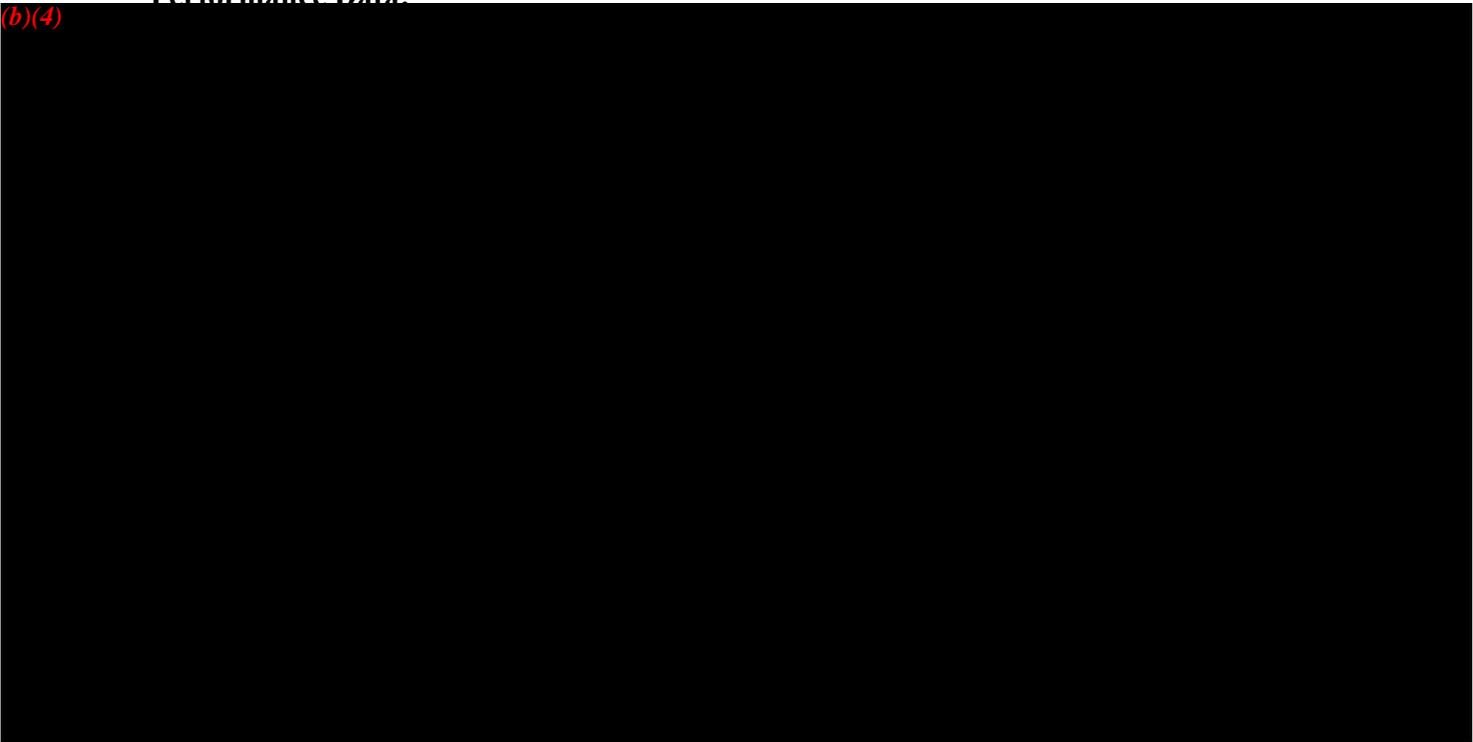
510(k) Summary

(b)(4)



Performance Data:

(b)(4)



Section 7

Truthful & Accurate Statement

7. Truthful and Accurate Statement

Pursuant to 21 CFR 807.87(j) I certify that in my capacity as Vice President, Quality/Regulatory/Clinical Affairs for Sonendo, 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.

Dan W. Miller
Sonendo, Inc.

Date

Section 7

Truthful & Accurate Statement

7. Truthful and Accurate Statement

Pursuant to 21 CFR 807.87(j) I certify that in my capacity as Vice President, Quality/Regulatory/Clinical Affairs for Sonendo, 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.



Dan W. Miller
Sonendo, Inc.

12/29/12

Date

Section 8

Class III Summary and Certification

8. Class III Summary and Certification

The Sonoendo Endotherapy System is a Class II medical device under 21 CFR 872.4850. The Class III Summary and Certification requirement as described in 21 CFR §807.87(j) and §807.94 do not apply to this device and submission.

Section 9

**Financial Certification
or Disclosure Statement**

9. Financial Certification or Disclosure Statement

The requirement for financial certification or disclosure requirement as described in 21 CFR §807.87(i) does not apply to this submission.

Section 10

**Declaration of Conformity
& Summary Reports**

10. Declaration of Conformity & Summary Reports

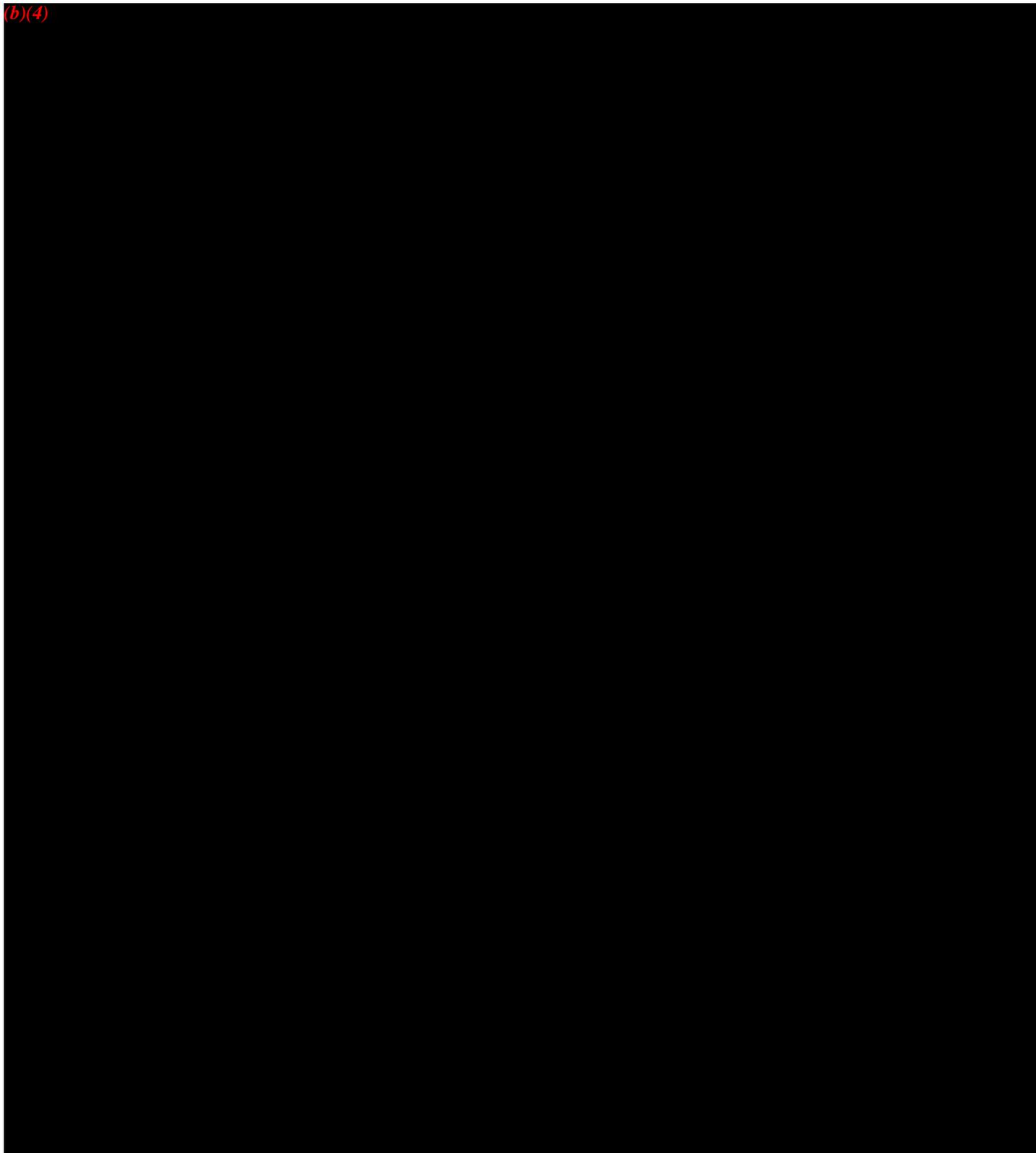
This submission is a traditional 510(k) submission. The requirement for a declaration of conformity and a summary report of testing does not apply.

Section 11

Executive Summary

11. Executive Summary

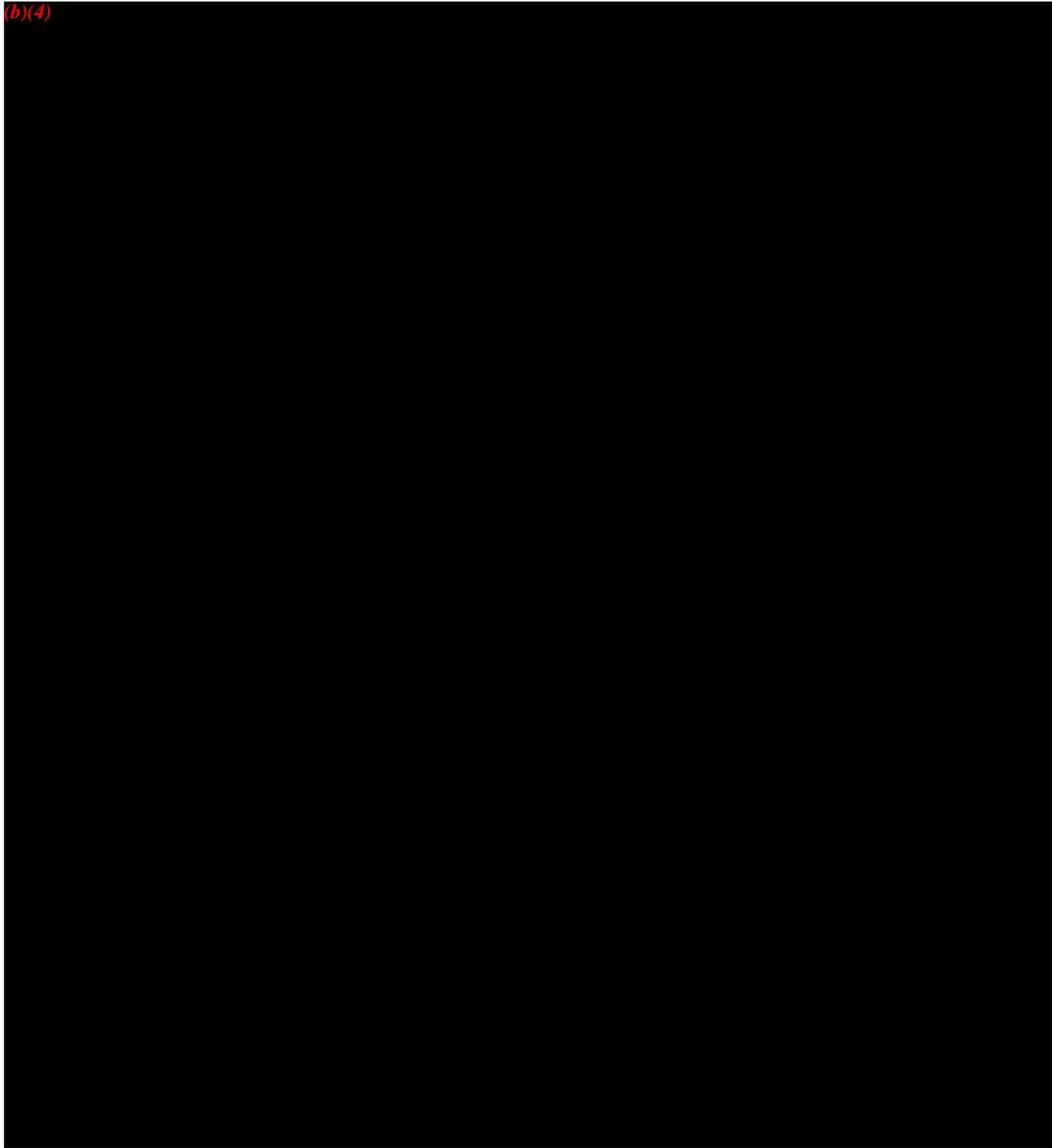
(b)(4)



Section 11

Executive Summary

(b)(4)





**Sonendo Endotherapy System
Molar Procedure Kit**

DRAFT

Instructions for Use

Federal law restricts this device to sale by or on the order of licensed dental professional

SONENDO

26061 Merit Circle, Suite 101

Laguna Hills, CA 92653

PH: 949-766-3636

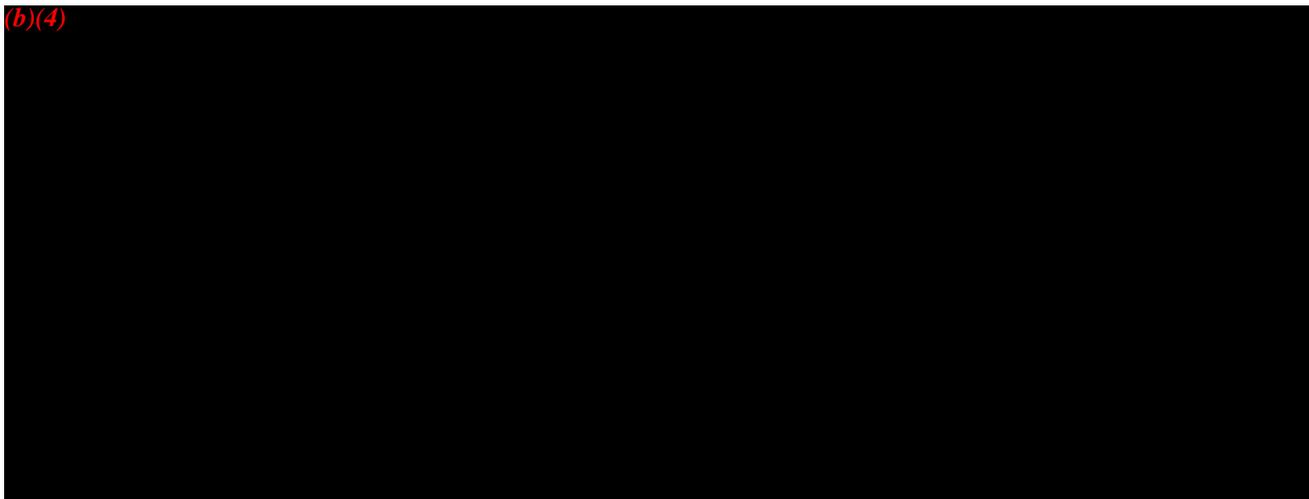
FAX: 949-348-1866

Section 15

Sterilization & Shelf Life

15. Sterilization and Shelf Life

(b)(4)



Sterilization Validation

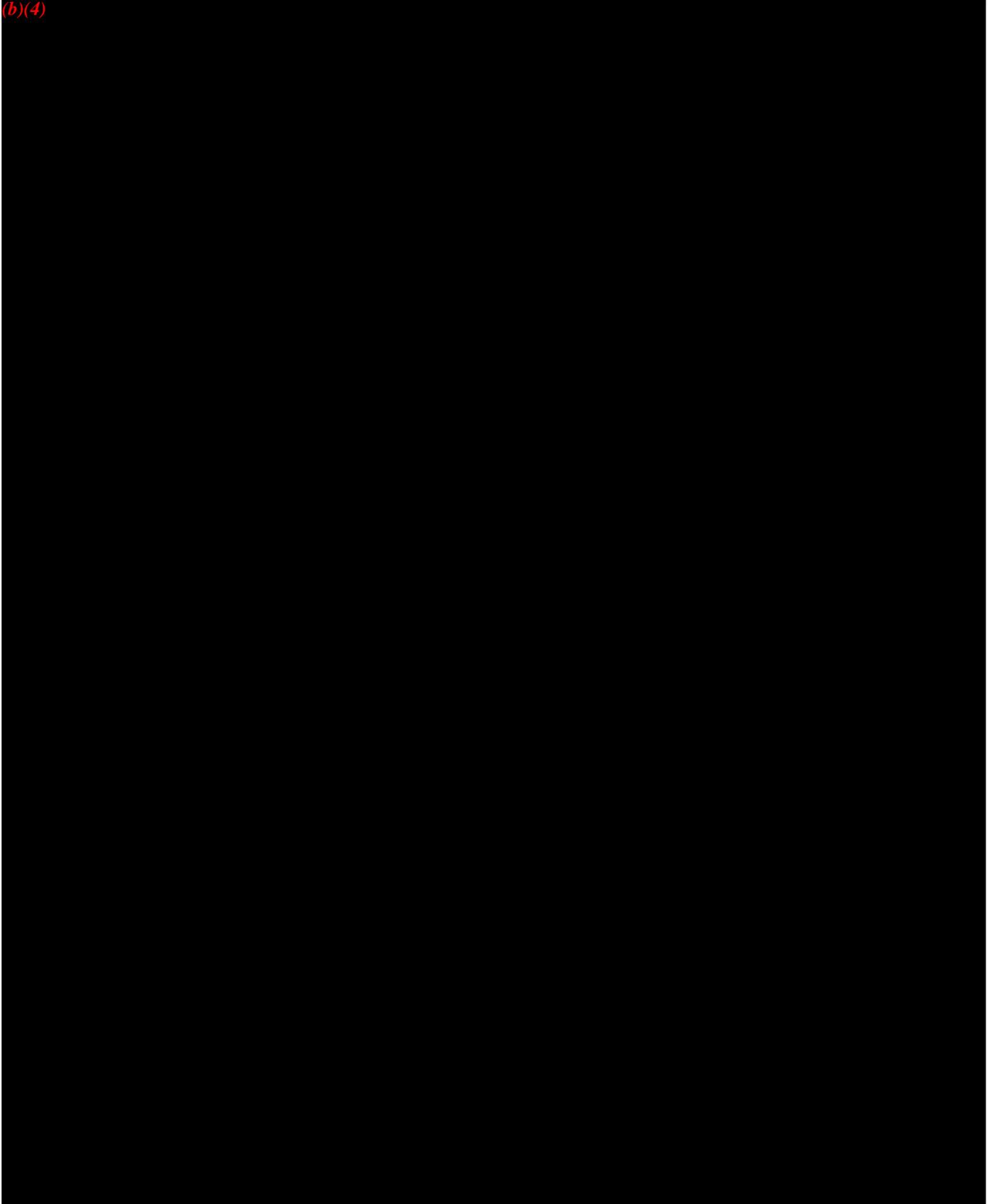
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Section 15

Sterilization & Shelf Life

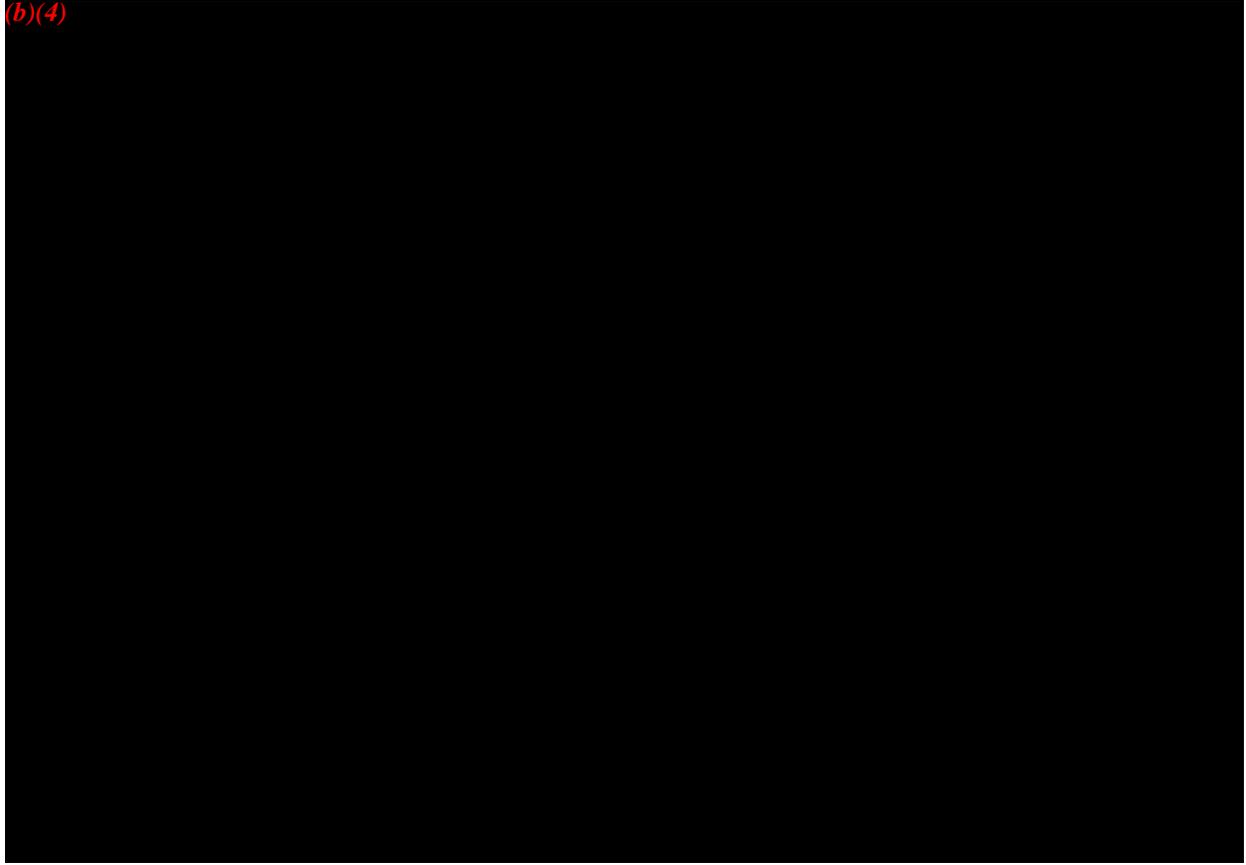
(b)(4)



Section 15

Sterilization & Shelf Life

(b)(4)

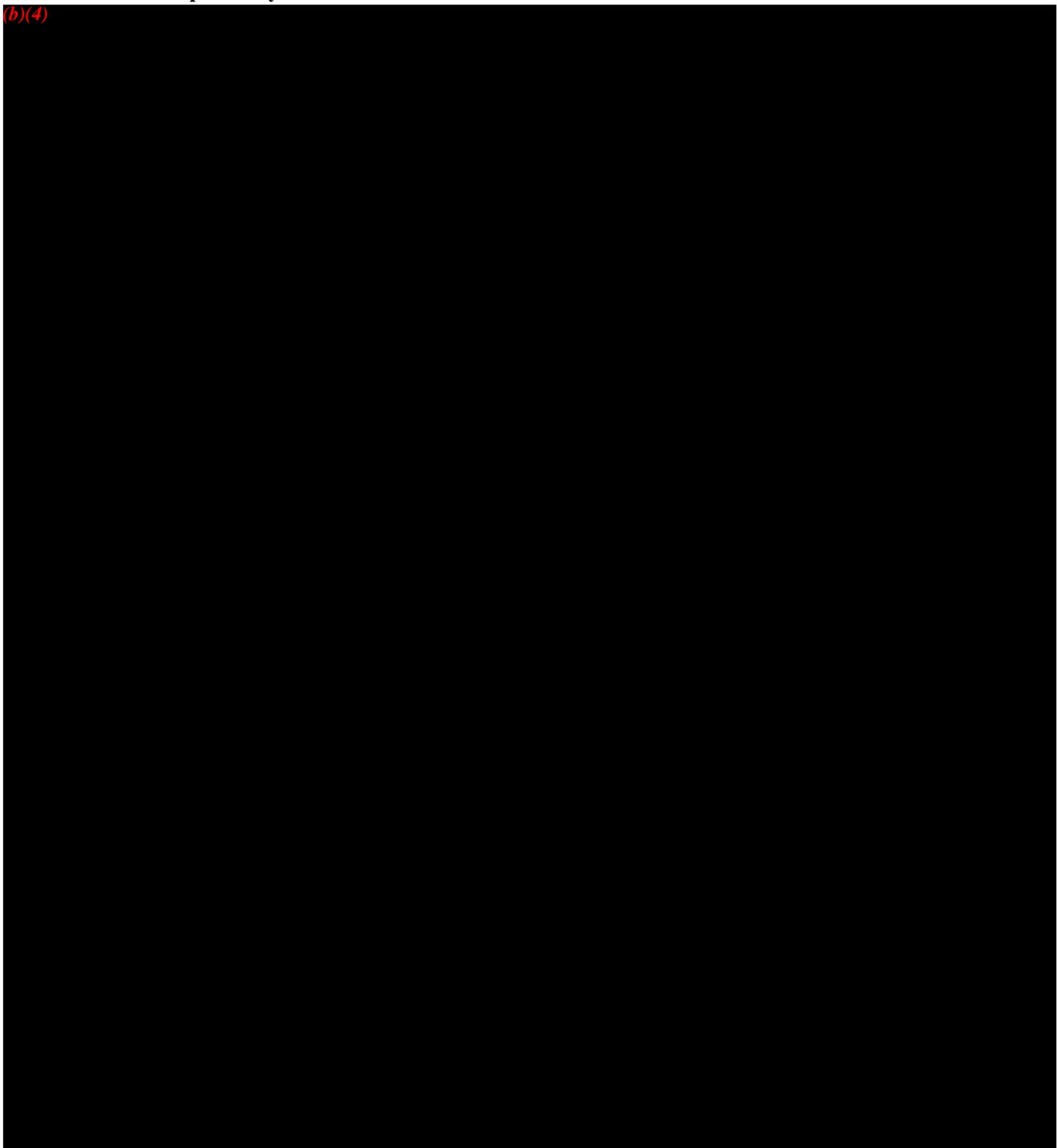


Section 16

Biocompatibility

16. Biocompatibility

(b)(4)

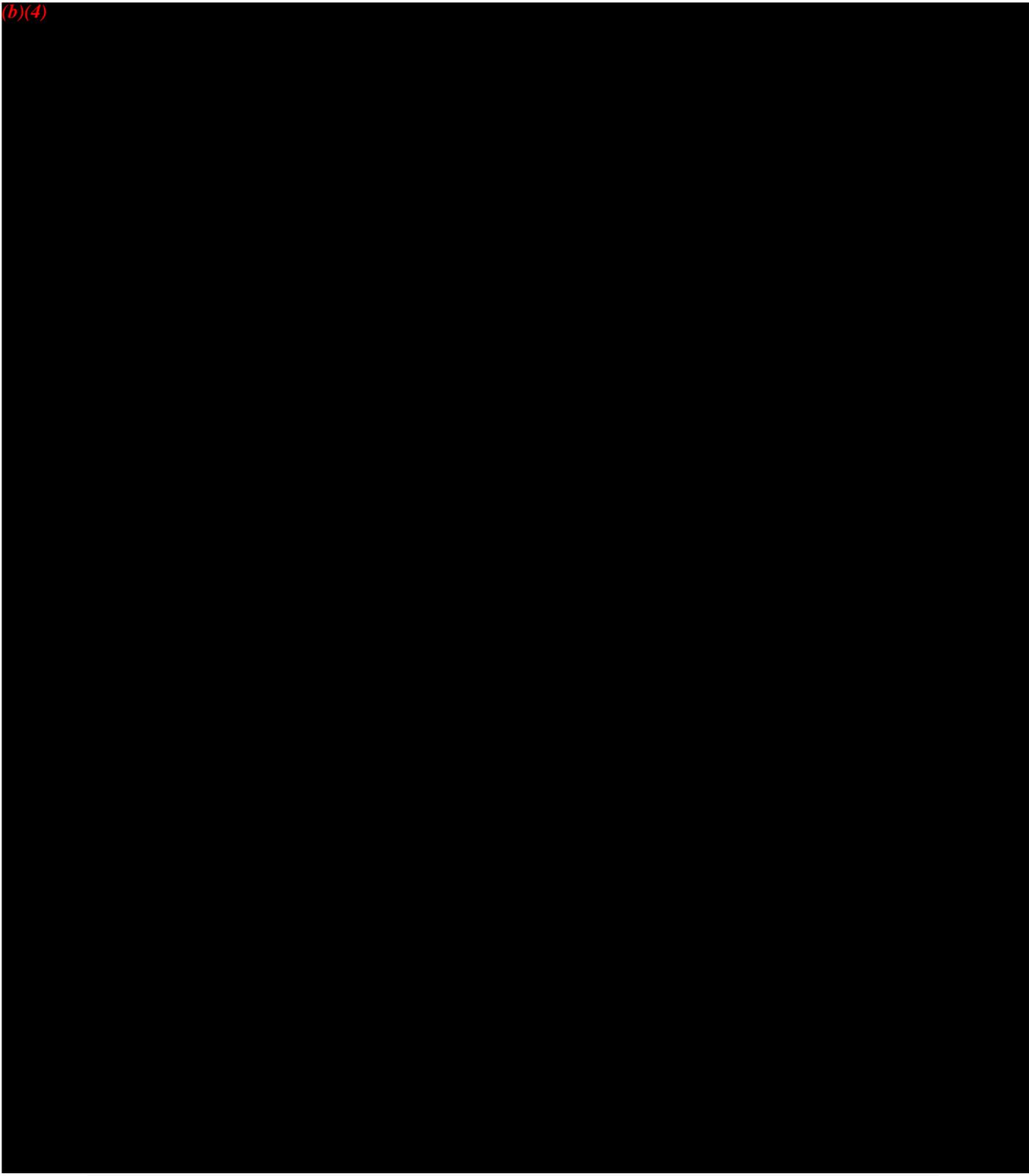


Section 17

Software

17. Software

(b)(4)

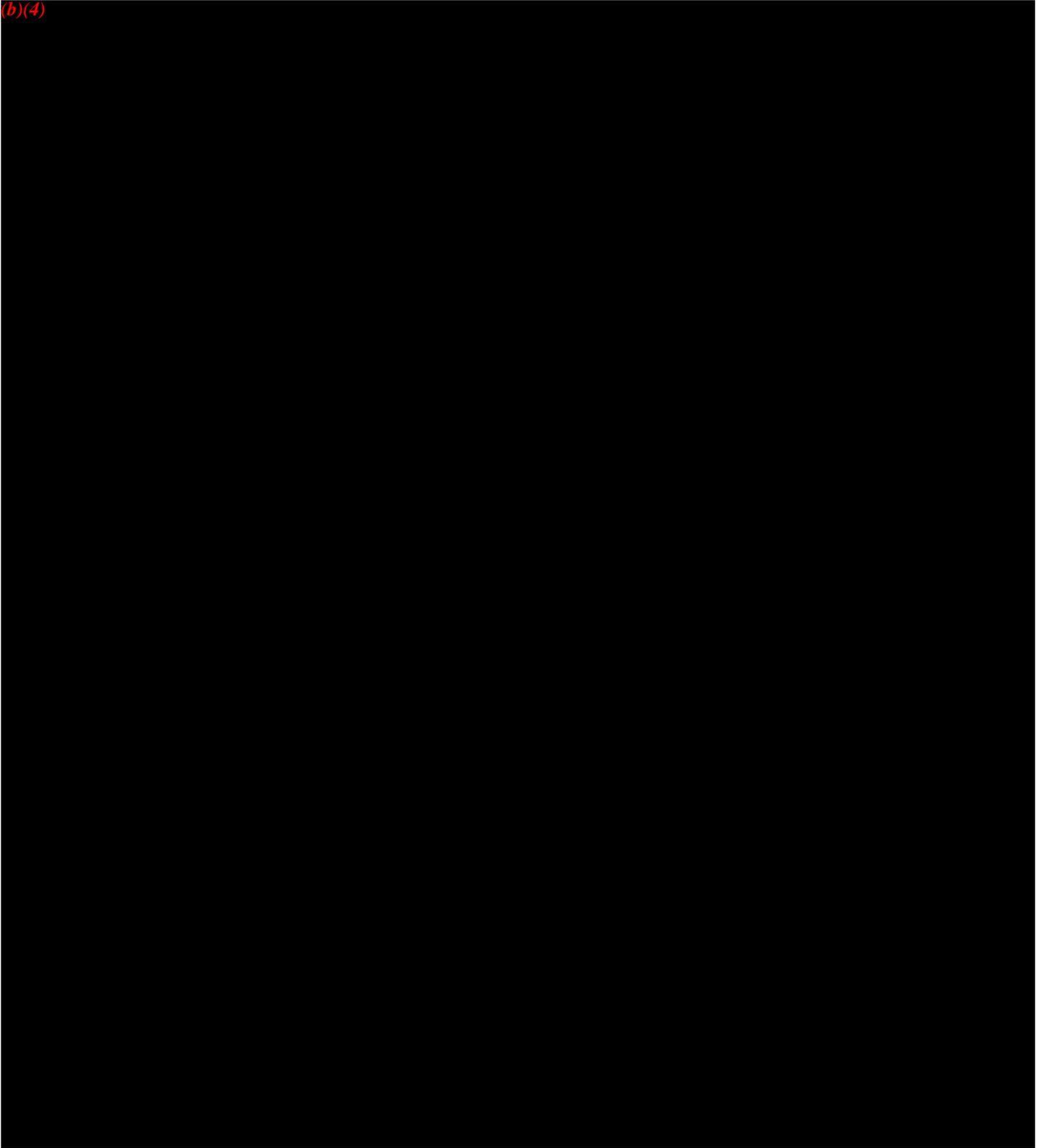


Section 19

Performance Testing- Bench

19. Performance Testing

(b)(4)



Appendices

Appendix 2 Sonendo Endotherapy System Technical Drawings

(see attached)

Appendices

Appendix 3 Sonendo Endotherapy System Biocompatibility Reports (see attached)



FINAL STUDY REPORT

STUDY TITLE:

PROTOCOL NUMBER:

TEST ARTICLE IDENTIFICATION:

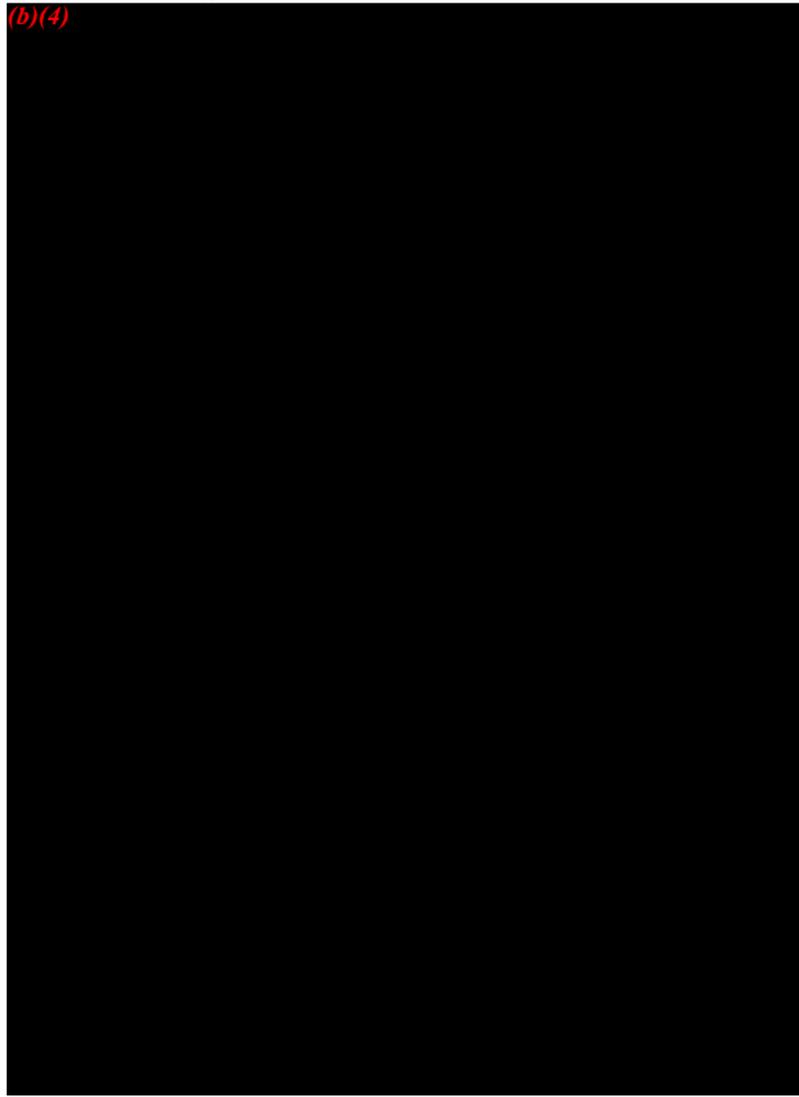
PERFORMING LABORATORY:

SPONSOR:

STUDY NUMBER:

CLIENT MNEMONIC:

RESULT SUMMARY:



	CONFIDENTIAL		Sonendo ®
	Title <i>(b)(4)</i>	Software Risk/Hazard Analysis	



Software Risk/Hazard Analysis

Appendices

Appendix 11 Sonendo Endotherapy System Electromagnetic Compatibility Test Report

(see attached)

(b)(4)



MEDICAL DEVICE DIRECTIVE 93/42/EEC

EMC EVALUATION

PER IEC/EN 60601-1-2

For The
Sonendo Endotherapy System
Model: **Sonendo Endotherapy System Console**

Prepared for:

Sonendo Inc
26051 Merit Circle, Suite 102
Laguna Hills, CA 92653

(b)(4)

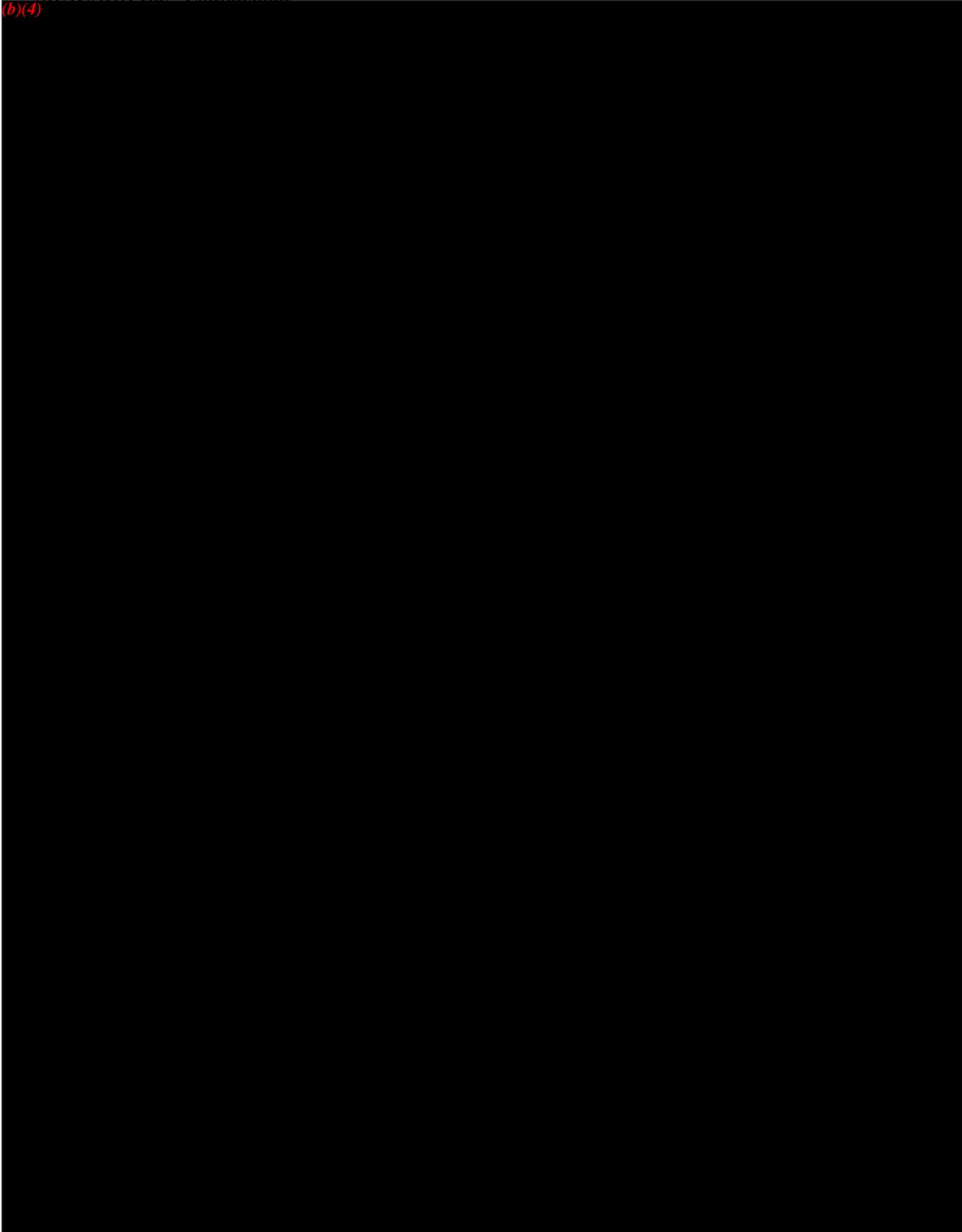
(b)(4)

Appendices

Appendix 13 (b)(4), Thermal Safety Experiment Report (see attached)

SONENDO Inc – Confidential

(b)(4)



Appendices

Appendix 17 Imaging of Cavitation Clouds

(see attached)



CONFIDENTIAL
(b)(4) Sonendo™

(b)(4)

(b)(4)

(b)(4)

Appendix I

Optical Analysis via Stereo Microscope (8x)

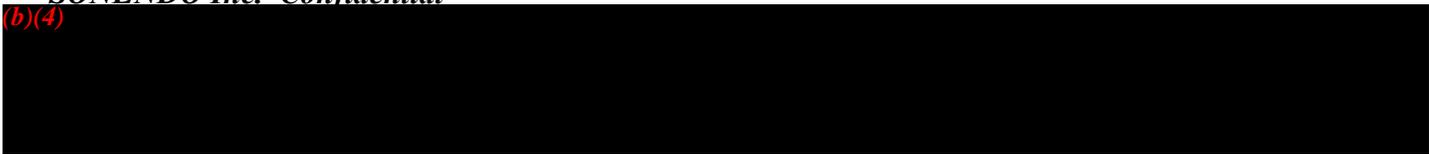
Thirteen specimens imaged at 8x magnification

Sonendo Endotherapy System

(b)(4)

SONENDO Inc.—Confidential

(b)(4)



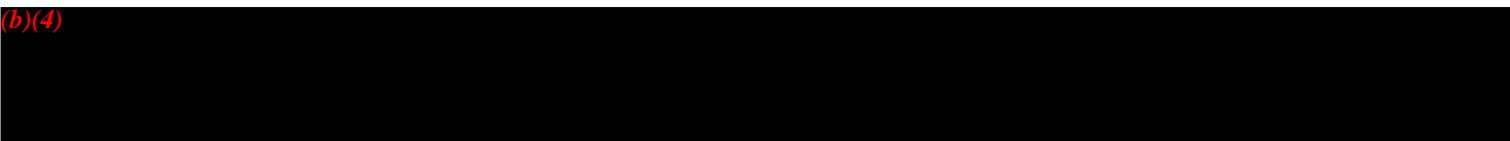
Appendix II

Optical Analysis via Stereo Microscope (8x)

Five specimens imaged at 8x magnification

EMS Piezon Master 700

(b)(4)



(b)(4)

Appendix III

Optical Analysis via Scanning Electron Microscope

Four canals imaged at 50x and 200x magnification

Sonendo Endotherapy System

(b)(4)

SONENDO Inc.—Confidential

(b)(4)



Appendix IV

Optical Analysis via Scanning Electron Microscope

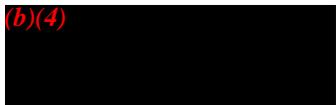
Four canals imaged at 50x and 200x magnification

EMS Piezon Master 700

(b)(4)



(b)(4)



* * * COMMUNICATION RESULT REPORT (JUN. 13. 2013 8:31PM) * * *

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : JUN. 13. 2013 8:29PM
FILE MODE OPTION

5507 MEMORY TX

ADDRESS

919493481866

RESULT

OK

PAGE

3/3

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-3) NO ANSWER

E-2) BUSY
E-4) NO FACSIMILE CONNECTION



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 11, 2013

Mr. Dan W. Miller
Sonendo, Incorporated
26061 Merit Circle, Suite 101
LAGUNA HILLS CA 92653

Re: K130025
Trade/Device Name: Sonendo Endotherapy System
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: May 7, 2013
Received: May 16, 2013

Dear Mr. Miller:

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.



COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

From: Reviewer Name Anita Belani
Subject: 510(k) Number K130025
To: The Record

Please list CTS decision code: SE - Substantially Equivalent

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

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

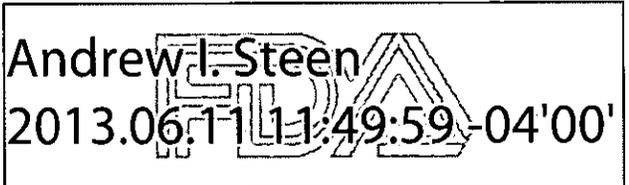
Nanotechnology		×
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		×

Regulation Number: 21CFR872.4850

Class: II

Product Code: ELC

Additional Product Codes:

Digital Signature Concurrence Table (Not all signatures may be required)	
Branch Chief Sign-Off	
Division Sign-Off	

K130025/131
K27



FDA CDRH DMC

January 17, 2013

JAN 22 2013

Received

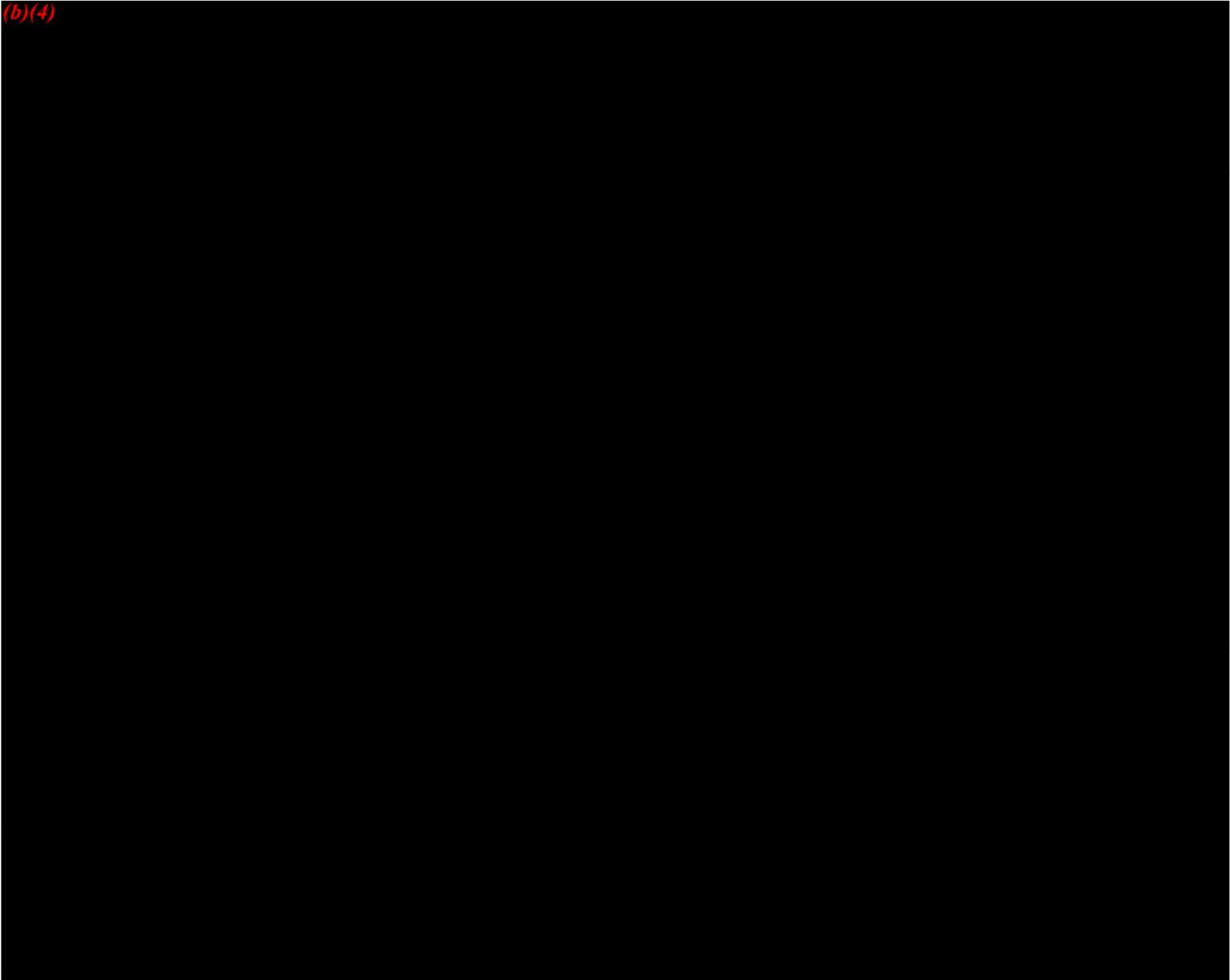
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (W066-0609)
10903 New Hampshire Avenue
Silver Springs, MD 20993-0002

RE: K130025/S001

Dear Dr. Belani,

In response to the January 16, 2013 Refuse to Accept notification; we have amended our application as follows:

(b)(4)





K130025/S002
FDA CDRH DMC
MAY 16 2013
Received

May 7, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (W066-0609)
10903 New Hampshire Avenue
Silver Springs, MD 20993-0002

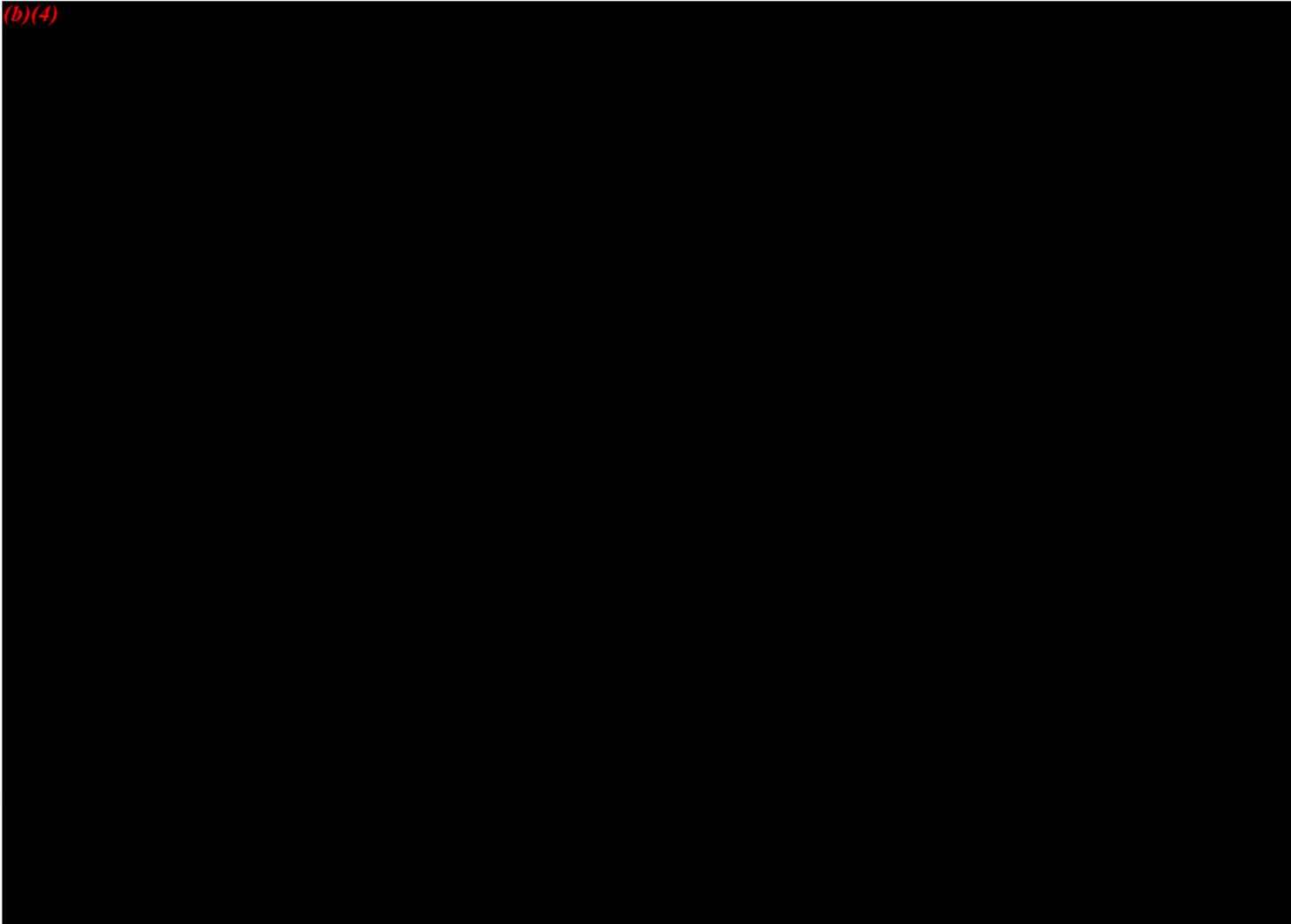
RE: K130025 Sonendo Endotherapy System - First Round Deficiencies Response

Dear Dr. Belani,

In response to the March 12, 2013 First Round Deficiencies notification; we have amended our application as follows:

Deficiencies

(b)(4)



DEPARTMENT OF HEALTH AND HUMAN SERVICES
 FOOD AND DRUG ADMINISTRATION

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

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission December 29, 2012	User Fee Payment ID Number MD6066279-956733	FDA Submission Document Number (if known) K130025
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SECTION A TYPE OF SUBMISSION

PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input checked="" type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Request for Feedback <input type="checkbox"/> Pre-Submission <input type="checkbox"/> Informational Meeting <input type="checkbox"/> Submission Issue Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Study Risk Determination <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Sonendo, Inc	Establishment Registration Number (if known)		
Division Name (if applicable) NA	Phone Number (including area code) 949-766-3636		
Street Address 26061 Merit Circle, Suit 101	FAX Number (including area code) 949-305-5201		
City Laguna Hills	State / Province CA	ZIP/Postal Code 92653	Country USA
Contact Name Dan Miller			
Contact Title Vice President of Regulatory/Clinical Affairs, and Quality Assurance		Contact E-mail Address dmiller@sonendo.com	

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

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

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

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

Other Reason (*specify*):

SECTION D2 REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent/Applicant <input type="checkbox"/> Design/Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		

Other Reason (*specify*):

SECTION D3 REASON FOR SUBMISSION - 510(k)

<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
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Other Reason (*specify*):

March 12, 2013: First Round Deficiencies Notification, Dr. Belani

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	ELC	2	3	
5		6	7	

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

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K093000	1	EMS Piezon Master 700	1	EMS Electro Medical Systems SA
2	K081268	2	Sonic Air MM 1500+ (MID)	2	Micro-Mega S.A.
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
 Ultrasonic Scaler

	Trade or Proprietary or Model Name for This Device		Model Number
1	Sonendo Endotherapy System	1	109-0008-001
2	Sonendo Endotherpay Molar Handpiece Kit	2	109-0006-001
3		3	
4		4	
5		5	

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

1	K130025	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 ELC	C.F.R. Section (if applicable) 21 CFR 872.4850	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel		

Indications (from labeling)
 The Sonendo Endotherapy System is intended to prepare, clean and irrigate 1st and 2nd molar teeth indicated for root canal therapy.

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

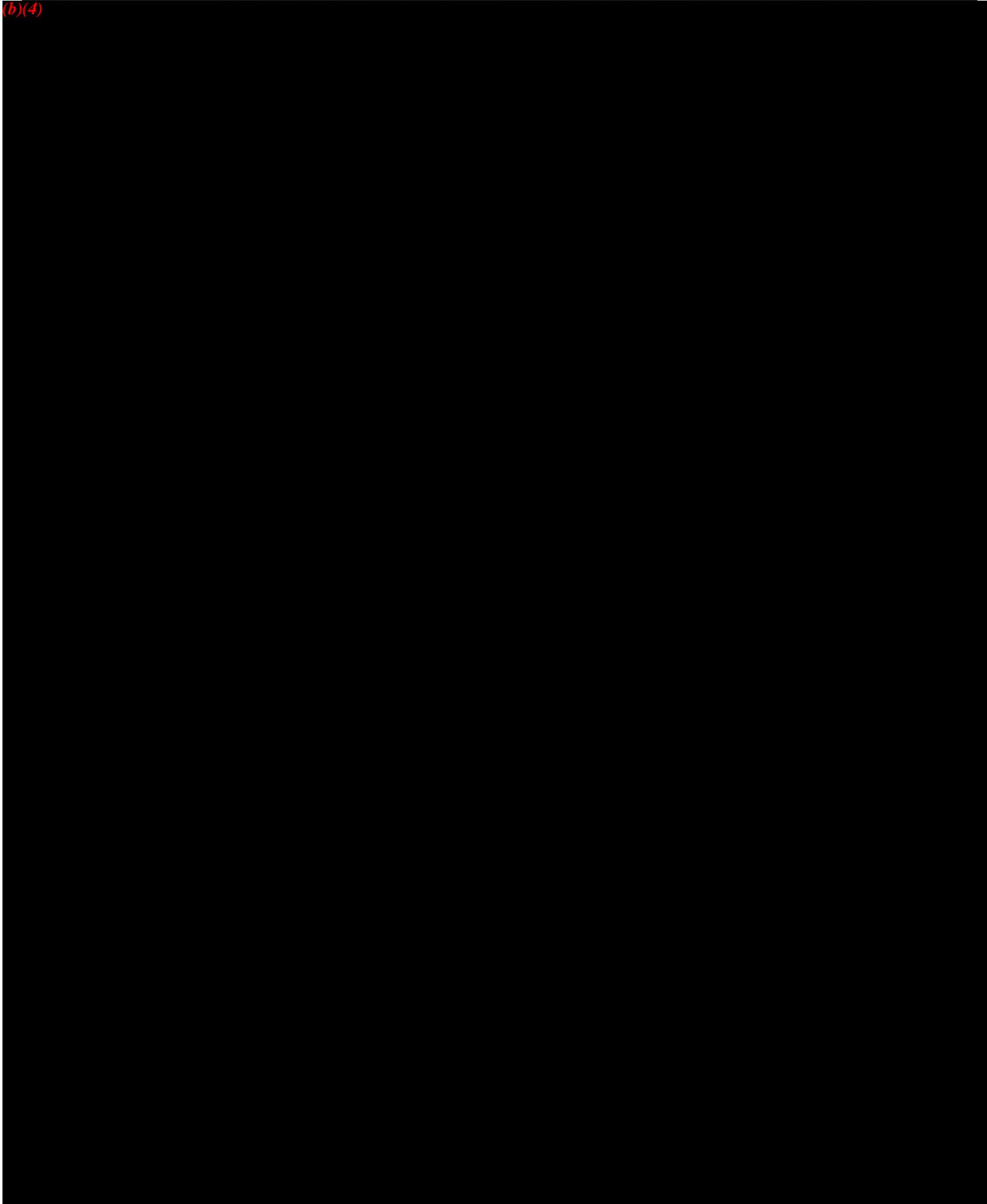
FDA Document Number *(if known)*

K130025

SECTION H

MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

(b)(4)



Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number <i>(if known)</i> K130025
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SECTION H (Continued)

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

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

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

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	ISO 10993-1	International Organization for Standardization	Biological Evaluation of Medical Device- Part 1 Evaluation and Testing	4	01/01/2009
2	ISO 10993-5	International Organization for Standardization	Biological Evaluation of Medical Device- Part 5 Tests for In Vitro Cytotoxicity	3	01/01/2009
3	ISO 10993-10	International Organization for Standardization	Biological Evaluation of Medical Device- Part 10 Tests for Irritation and Delayed Hypersensitivity	3	01/01/2010
4	ISO 10993-11	International Organization for Standardization	Biological Evaluation of Medical Device- Part 11 Tests for Systemic Toxicity	2	01/01/2006
5	ISO 11137-1	International Organization for Standardization	Sterilization of Health Care Products- Radiation- Part 1 Requirements for Development of Validation	1	01/01/2006
6	ISO 11137-2	International Organization for Standardization	Sterilization of Health Care Products- Radiation- Part 2 Establishing Sterilization Dose	2	01/01/2006
7	IEC 60601-1-1-2	International Electrotechnical Commission	Medical electrical equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests	3	01/01/2007

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

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

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

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

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

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

FDA FORM 3514

K130025: Section I Utilization of Standards (continued)

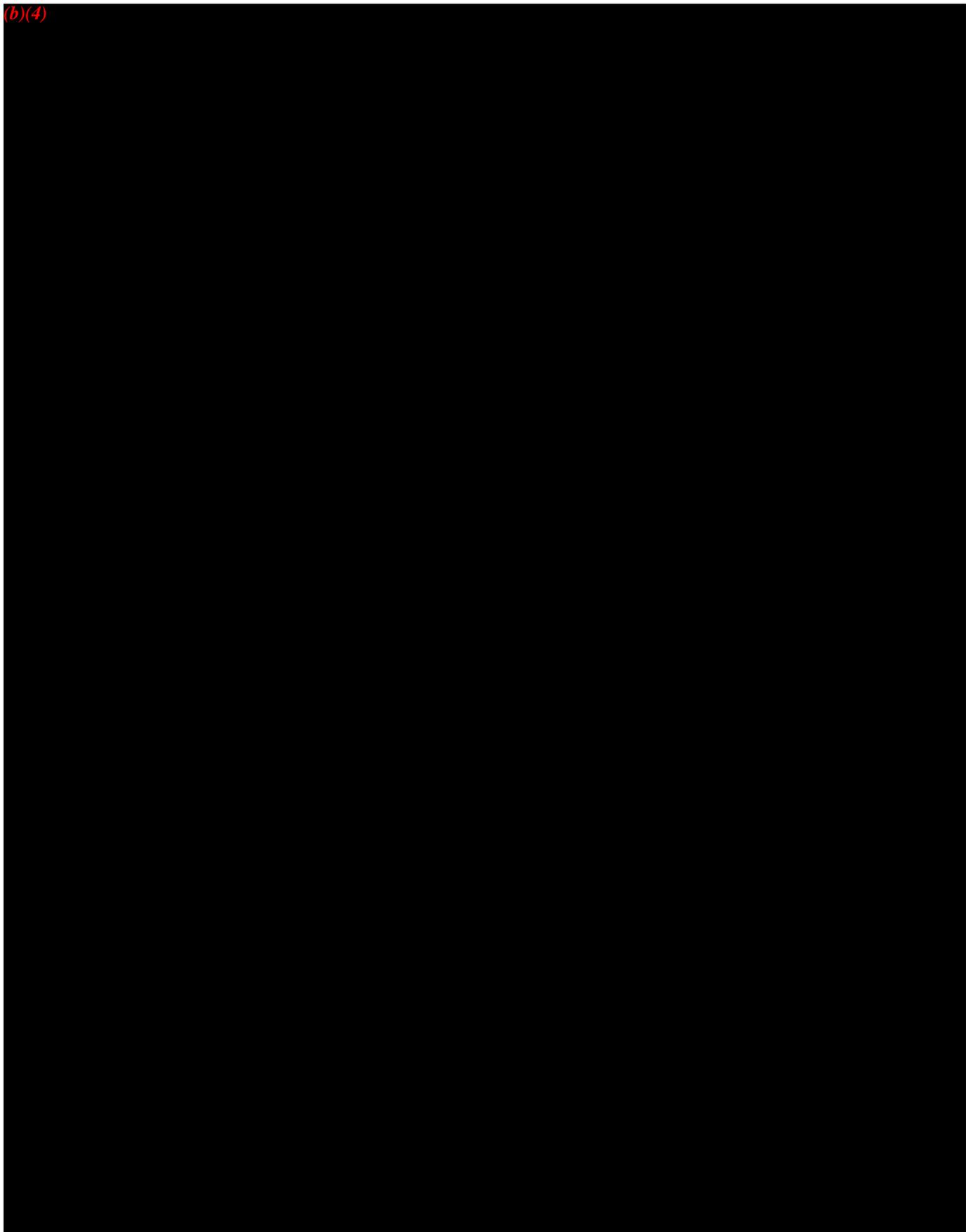
#	Standards No.	Standards Organization	Standards Title	Version	Date
8	IEC 60601-1	International Electrotechnical Commission	Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995	3	01/01/2006
9	ISO 11607-1	International Organization for Standardization	Packaging for terminally sterilized medical devices - - Part 1: Requirements for materials, sterile barrier systems and packaging systems	1	01/01/2006

Section 19

Performance Testing- Bench

19. Performance Testing

(b)(4)



(b)(4)



Software Risk Hazard and Traceability Analysis

(b)(4)

(b)(4)