U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K073690 - 192 pages
COMPANY:	INTERLACE MEDICAL, INC. (INTEMEDIY)
PRODUCT:	HYSTEROSCOPE (AND ACCESSORIES) (HIH)
SUMMARY:	Product: INTERLACE MEDICAL HYSTEROSCOPIC MORCELLATION SYSTEM
DATE REQUESTED:	Oct 5, 2015
DATE PRINTED:	Oct 5, 2015

Note: Printed

K073690

APR 17 2008

Interlace Medical
Hysteroscopic Morcellation System
510K Summary of Safety and Effectiveness
April 11, 2008

1. Sponsor Name

   Sponsor/Manufacturer
   Interlace Medical Inc.
   139 Newbury St
   Framingham, MA 01701
   Telephone: 508.875.1343

2. Device Name

   Proprietary Name: Interlace Medical Hysteroscopic Morcellation System
   Common/Usual Name: Hysteroscope and accessories

3. Identification of Predicate or Legally Marketed Device

   The Interlace Medical Hysteroscopic Morcellation System is substantially equivalent to the Smith and Nephew Hysteroscopic Morcellation System K041774.

4. Device Description

   The system consists of the following components:

   - Control Unit
   - Morcellator Handpiece
   - Single Use Morcellator
   - Footswitch

   The Interlace Medical Hysteroscopic Morcellation System will be used with standard hysteroscopes and fluid management systems.

5. Intended Use

   The Interlace Medical Hysteroscopic Morcellation System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

6. Comparison of Technological Characteristics

The principles of operation of the Interlace Medical Hysteroscopic Morcellation System are identical to those of the predicate device, the Smith and Nephew Hysteroscopic Morcellation System K041774. A disposable straight surgical morcellator is inserted into a morcellator handpiece for tissue removal. A footswitch is used to turn the morcellator on and off. The morcellator consists of a rotating and reciprocating inner tube or cutter that is totally contained within an outer tube and has a fitting at its proximal end to which vacuum tubing is attached. The outer tube incorporates a "cutting window" through which targeted tissue is pulled, cut, and moved back through the inner tube to a collection canister.

7 Performance Testing

The Interlace Medical Hysteroscopic Morcellation System meets electrical safety and EMC standards. In addition, an in-vitro test was conducted which demonstrated that the device performs equivalent to or better than the predicate device.

8. Statement of Equivalency

The Interlace System is substantially equivalent in design, materials, construction and intended use as that of the predicate. The principal of operation of both devices are exactly the same. Since the Interlace Morcellator has the same in intended use and technological characteristics as the predicate device, the Interlace Morcellator does not raise any new safety and efficacy concerns when compared to the similar legally marketed device.

The descriptive characteristics demonstrate that the Interlace Morcellator is substantially equivalent to the predicate device and is capable of safely and accurately performing the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 17 2008

Mr. Ron Adams
Chief Technical Officer
Interlace™ Medical
139 Newbury Street
FRAMINGHAM MA 01701

Re: K073690
Trade/Device Name: Interlace Medical Hysteroscopic Morcellation System
Regulation Number: 21 CFR §884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: March 27, 2008
Received: March 28, 2008

Dear Mr. Adams:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073690

Device Name: Interlace Medical Hysteroscopic Morcellation System

Indications For Use:

The Interlace Medical Hysteroscopic Morcellation System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073690

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 1/20/2011

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K073690/A1

To: Division Director: OB/DRGUD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

_____ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: _____

Date: _____

POS

3/9/11

K073690/A1

Interlace MEDICAL

FDA CDRH DMC

JAN 19 2011

Received

FDA CDRH DMC

JAN 10 2011

Received

January 17, 2011

Food and Drug Administration
Center for Devices and Radiological Health - Office of Device Evaluation
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Attention: Document Control Clerk
RE: Notification of Change in 510(k) Ownership

Dear Sir or Madam,

As announced in the below 1/7/2011 press release, Interlace Medical, Inc. has been acquired by Hologic, Inc.

Posted on: Friday, 7 January 2011, 06:00 CST

BEDFORD, Mass., Jan. 7, 2011 /PRNewswire/ – Hologic, Inc. (Hologic or the Company) (Nasdaq: HOLX), a leading developer, manufacturer and supplier of premium diagnostics, medical imaging systems and surgical products dedicated to serving the healthcare needs of women, announced today it has acquired Interlace Medical, Inc. (Interlace), the developer and manufacturer of the MyoSure hysteroscopic tissue removal system (MyoSure). Interlace's operations will be integrated within Hologic's GYN Surgical Products division.

Attached, please find letters of notification for a change in ownership for the following pre-market notifications:

510(k) #:	Device Name:
K073690	Interlace Medical Hysteroscopic Morcellation System
K081070	Interlace Medical Operative Hysteroscopy System
K091100	MyoSure™ Hysteroscopic Tissue Removal System
K091465	MyoSure™ Rod Lens Hysteroscope
K100559	MyoSure™ Hysteroscopic Tissue Removal System
K102686	MyoSure™ Single Use Seals

Please place copies of the letters in the relevant 510(k) files and feel free to contact me directly at (508) 875-1343, extension 112 if questions arise concerning this notification.

Sincerely,

John Vozella

John J. Vozella
V.P. Clinical & Regulatory Affairs
Interlace Medical, Inc.
135 Newbury Street
Framingham, MA 01701

K073690

Interlace MEDICAL

January 17, 2011

FDA CDRH DMC

JAN 19 2011

Received

Food and Drug Administration
Center for Devices and Radiological Health - Office of Device Evaluation
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Attention: Document Control Clerk
RE: K073690 - 510(k) Supplement - Notification of Change in 510(k) Ownership

Dear Sir or Madam,

As announced in the below 1/7/2011 press release, Interlace Medical, Inc. has been acquired by Hologic, Inc.

Posted on: Friday, 7 January 2011, 06:00 CST

BEDFORD, Mass., Jan. 7, 2011 /PRNewswire/ -- Hologic, Inc. (Hologic or the Company) (Nasdaq: HOLX), a leading developer, manufacturer and supplier of premium diagnostics, medical imaging systems and surgical products dedicated to serving the healthcare needs of women, announced today it has acquired Interlace Medical, Inc. (Interlace), the developer and manufacturer of the MyoSure hysteroscopic tissue removal system (MyoSure). Interlace's operations will be integrated within Hologic's GYN Surgical Products division.

Pursuant to this transaction, effective 1/7/2011, all assets of Interlace Medical are now owned by Hologic, Inc., and all right, title and interest in the following 510(k) has been transferred from Interlace Medical, Inc. to Hologic, Inc.:

510(k) #: K073690
Device Name: Interlace Medical Hysteroscopic Morcellation System

Please place a copy of this letter in the relevant 510(k) file and feel free to contact me directly at (508) 875-1343, extension 112 if questions arise concerning this notification.

Sincerely,

John Vozella

John J. Vozella
V.P. Clinical & Regulatory Affairs
Interlace Medical, Inc.

Interlace MEDICAL

January 17, 2011

Food and Drug Administration
Center for Devices and Radiological Health - Office of Device Evaluation
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Attention: Document Control Clerk
RE: K073690 - 510(k) Supplement - Notification of Change in 510(k) Ownership

Dear Sir or Madam,

As announced in the below 1/7/2011 press release, Interlace Medical, Inc. has been acquired by Hologic, Inc.

Posted on: Friday, 7 January 2011, 06:00 CST

BEDFORD, Mass., Jan. 7, 2011 /PRNewswire/ – Hologic, Inc. (Hologic or the Company) (Nasdaq: HOLX), a leading developer, manufacturer and supplier of premium diagnostics, medical imaging systems and surgical products dedicated to serving the healthcare needs of women, announced today it has acquired Interlace Medical, Inc. (Interlace), the developer and manufacturer of the MyoSure hysteroscopic tissue removal system (MyoSure). Interlace's operations will be integrated within Hologic's GYN Surgical Products division.

Pursuant to this transaction, effective 1/7/2011, all assets of Interlace Medical are now owned by Hologic, Inc., and all right, title and interest in the following 510(k) has been transferred from Interlace Medical, Inc. to Hologic, Inc.:

510(k) #: K073690
Device Name: Interlace Medical Hysteroscopic Morcellation System

Please place a copy of this letter in the relevant 510(k) file and feel free to contact me directly at (508) 875-1343, extension 112 if questions arise concerning this notification.

Sincerely,

John Vozella

John J. Vozella
V.P. Clinical & Regulatory Affairs
Interlace Medical, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 17 2008

Mr. Ron Adams
Chief Technical Officer
Interlace™ Medical
139 Newbury Street
FRAMINGHAM MA 01701

Re: K073690
Trade/Device Name: Interlace Medical Hysteroscopic Morcellation System
Regulation Number: 21 CFR §884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: March 27, 2008
Received: March 28, 2008

Dear Mr. Adams:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073690

Device Name: Interlace Medical Hysteroscopic Morcellation System

Indications For Use:

The Interlace Medical Hysteroscopic Morcellation System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073690

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 07, 2008

INTERLACE MEDICAL, INC.
139 NEWBURY STREET
FRAMINGHAM, MA 01701
ATTN: RON ADAMS

510(k) Number: K073690
Product: INTERLACE MEDICAL HYSTEROSCOPIC MORCELLATION

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.
Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 31, 2007

INTERLACE MEDICAL, INC.
139 NEWBURY STREET
FRAMINGHAM, MA 01701
ATTN: RON ADAMS

510(k) Number: K073690
Received: 28-DEC-2007
Product: INTERLACE MEDICAL HYSTEROSCOPIC MORCELLATION SYSTEM

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

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/cdrh/mdufma/index.html for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf.

A new provision of the Food and Drug Administration Amendments Act of 2007, 42 U.S.C. 282(j)(5)(B), requires that a certification form (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf) accompany all 510(k)/HDE/PMA submissions on or after December 26, 2007. You are responsible for registering certain device clinical trials in the Clinical Trials Data Bank (http://prsinfo.clinicaltrials.gov). If your submission does not include FDA Form 3674, please send 2 hardcopies of the completed certification form referencing the submission number identified above. Additional information about the new certification

form may be found at the following link to the Federal Register Notice (http://www.fda.gov/OHRMS/DOCKETS/98fr/07-6023.htm).

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k). 2)Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

K073690

Interlace Medical Inc.
Hysteroscopic Morcellation System

Premarket Notification

Interlace Medical Inc.
139 Newbury St
Framingham, MA 01701

FDA CDRH DMC
DEC 28 2007
Received

December 28, 2007

Food and Drug Administration
Center for Devices and Radiological Health -
Office of Device Evaluation
510(k) Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

RE: Premarket Notification for the Interlace Medical Hysteroscopic Morcellation System

Dear Sir/Madam:

Pursuant to 21 CFR 807.90 Interlace Medical Inc., 139 Newbury St, Framingham, MA 01701 is submitting two copies of this 510(k) notification for the Interlace Medical Hysteroscopic Morcellation System.

Section I of this document contains a completed copy of the "Premarket Submission Cover Sheet" and the "Premarket Notification 510(k) Checklist for Acceptance Decision" with reference to the sections of this document that contain the required information, and an "Indications For Use Statement". The "510(k) Summary of Safety and Effectiveness Information" can be found in Section VIII.

This notification thoroughly describes the intended use and technological features of the Interlace Medical Hysteroscopic Morcellation System and those of its predicates.

Interlace Medical Inc. requests that the FDA keeps and maintains confidential both the existence and the contents of this Premarket Notification in accordance with 21 CFR 807.95(b). Interlace Medical Inc. also requests that the FDA keeps and maintains confidential the contents of this letter.

We are eager to provide any necessary assistance during your evaluation of this submission. If you have any questions about this Premarket notification, the contact person is: Ron Adams at 508.875.1343.

Sincerely,

Ron Adams

Ron Adams
Chief Technical Officer

K21
OB
II

Form Approved: OMB No 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

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

PAYMENT IDENTIFICATION NUMBER: **MD6034126-956733**
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

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

INTERLACE MEDICAL
139 Newbury Street
Framingham MA 01701
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
562524653

2. CONTACT NAME
David Jacobs

2.1 E-MAIL ADDRESS
dj@interlacemedical.com

2.2 TELEPHONE NUMBER (include Area code)
508-8751343

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
null-null

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/dc/mdufma

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

3.1 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. 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, parents, and partner firms
[ ] This biologics application is submitted under secion 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

6. 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

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
$3,404.00 17-Dec-2007

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Interlace Medical Inc.
Hysteroscopic Morcellation System
Premarket Notification

TABLE OF CONTENTS

Section	Description	Page Number
Section I.	General Information	
	A. PreMarket Cover Sheet	000001
	B. DRAERD Reviewers Screening Checklist	000006
	C. Truthful and Accurate Statement	000010
	D. Indication for Use Statement	000011
	E. Company Name and Address	000012
	F. Device Name	000012
	G. Establishment Registration Number	000012
	H. Device Classification	000012
	I. Performance Standards	000012
	J. Labeling – Instructions for Use and Device Labels	000012
Section II.	Device Description	000013
Section III	Substantial Equivalence Rationale	000016
Section IV	Performance Testing	000020
Section V	Sterilization and Biocompatibility	000021
Section VI	Kit Certification	000022
Section VII	Software	000023
Section VIII	Summary of Safety and Effectiveness	000024
Section IX	Attachments	
	1. Device Labeling	000026
	2. Device Drawings	000050
	3. Predicate Device Labeling and Information	000055
	4. Performance Data	000065
	5. 510K Summary of Safety and Effectiveness	000080

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: September 30, 2004.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
12/28/2007	MD6034126-956733	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (120 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ 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: Interlace Medical Inc	Establishment Registration Number *(if known)*: TBD		
Division Name *(if applicable)*:	Phone Number *(including area code)*: (508) 875.1343		
Street Address: 139 Newbury St	FAX Number *(including area code)*: (508) 370.8026		
City: Framingham	State / Province: MA	ZIP/Postal Code: 01701	Country: US
Contact Name: Ron Adams			
Contact Title: CTO	Contact E-mail Address: Ron@InterlaceMedical.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/Postal Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

102

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

- [ ] 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

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

- [ ] Location change:
  - [ ] Manufacturer
  - [ ] Sterilizer
  - [ ] Packager

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

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

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

- [ ] Response to FDA correspondence:

- [ ] 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

- [ ] Repose 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)

- [x] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [ ] Other Reason *(specify)*:

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	HIH	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 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	K041774	1	IUR Reciprocating Morcellator	1	Smith and Nephew
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

Hysteroscope and accessories

	Trade or Proprietary or Model Name for This Device		Model Number
1	Interlace Medical Hysteroscopic Morcellation System	1	TBD
2		2	
3		3	
4		4	
5		5	

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

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

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
HIH	884.1690	[ ] Class I [x] [redacted]
Classification Panel: Obstetrics/Gynecology		[ ] Class III [ ] Unclassified

Indications *(from labeling)*

The Interlace Medical Hysteroscopic Morcellation System is intended for use in gynecological procedures by trained gynecologists to resect and remove endometrial tissue for the following indications: Submucous myomas, Endometrial polyps

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

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

☑ Original ☐ Add ☐ Delete	FDA Establishment Registration Number TBD	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name Interlace Medical Inc		Establishment Registration Number TBD		
Division Name *(if applicable)*		Phone Number *(including area code)* (508) 875.1343		
Street Address 139 Newbury St		FAX Number *(including area code)* (508) 370.8026		
City Framingham		State / Province MA	ZIP Code 01701	Country US
Contact Name Ron Adams	Contact Title CTO		Contact E-mail Address ron@interlacemedical.com	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
eet Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
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 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/EN	Medical electrical equipment – Part 1: General requirements for safety	2004	
2	60601-1-1	IEC/EN	Medical electrical equipment. Part 1: General requirements for safety - 1. Collateral standard: Safety requirements for medical electrical systems	2000	
3	60601-1-2	IEC/EN	Medical Electrical Equipment. General Requirements for Safety- Collateral Standard: Electromagnetic Compatibility Requirements and Tests	2001	
4	60601-2-18	IEC/EN	Medical electrical equipment -- Part 2: Particular requirements for the safety of endoscopic equipment	1996	
	11135	ANSI/AAMI/ISO	Medical Devices-Validation and routine control of ethylene oxide sterilization.	1994	
6					
7					

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

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

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

a 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

SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS 510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

X Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present	**Inadequate or Missing**
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510(k)] Manual.	XX	
Table of Contents.	XX	
Truthful and Accurate Statement.	Page 10	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	Page 12	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	Page 12	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510(k)] Manual.	Page 26	
Statement of Indications for Use that is on a separate page in the premarket submission.	Page 11	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510(k)] Manual.	Page 16	
510(k) Summary or 510(k) Statement.	Page 80	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	Page 13	
Identification of legally marketed predicate device. *	Page 16	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	Page 12	
Class III Certification and Summary. **	NA	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	NA	
510(k) Kit Certification ***	NA	

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission: Not applicable

	Present	Inadequate or Missing
Name and 510(k) number of the sponsor's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor's unmodified predicate device.		
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.		
A Design Control Activities Summary that includes the following elements (a-e):	(no entry here)	(no entry here)
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission: NA

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity **[**For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.]**		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	Page 21	
b) Sterilization and expiration dating information:	Page 21	
i) sterilization process	Page 21	
ii) validation method of sterilization process	Page 21	
iii) SAL	Page 21	
iv) packaging	Page 21	
v) specify pyrogen free	NA	
vi) ETO residues	Page 21	
vii) radiation dose	NA	
c) Software Documentation:	NA	

Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the " Missing" column must be submitted before substantive review of the document.

Passed Screening _____Yes _____No

Reviewer:_____

Concurrence by Review Branch:_____

Date:_____

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

Truthful and Accuracy Statement

Pursuant to 21 CFR § 807.87(j), I certify that, in my capacity as the President of Interlace Medical 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.

William Gruber
President

December 28, 2007

Indications for Use

510(k) Number (if known): TBD

Device Name: Interlace Medical Hysteroscopic Morcellation System

Indications For Use:

The Interlace Medical Hysteroscopic Morcellation System is intended for use in gynecological procedures by trained gynecologists to resect and remove endometrial tissue for the following indications:

- Submucous myomas
- Endometrial polyps

CHANGED

Prescription Use _X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section I. General Information

Company Name and Address

Sponsor/Manufacturer
Interlace Medical Inc.
139 Newbury St
Framingham, MA 01701

Telephone: 508.875.1343
Contact Individual: Ron Adams, Chief Technical Officer

Device Name

Proprietary Name: Interlace Medical Hysteroscopic Morcellation System
Common/Usual Name: Hysteroscope and accessories

Establishment Registration Number

Interlace Medical has not yet registered but intends to do so prior to marketing

Device Classification

Panel: Obstetrics/Gynecology
Classification Name: Hysteroscope and accessories
CFR Number: 884.1690
Product Code: HIH

Performance Standards

To the best of our knowledge there are no performance standards applicable to these devices that have been adopted under section 514 of the Act.

Labeling and Instructions for Use

The labeling and instructions for use for the Interlace Medical Hysteroscopic Morcellation System can be found in Attachment 1.

Section II Device Description

The Interlace Medical Hysteroscopic Morcellation System is designed to meet the requirements of intrauterine morcellation. It is intended for use in gynecological procedures to resect and remove endometrial tissue for the following indications: Submucous myomas, Endometrial polyps. REVISED

The Interlace Morcellator System is a multiple-use device that is intended for the morcellation and removal of tissue under hysteroscopic visualization. The Interlace Medical Hysteroscopic Morcellation System will be used with standard hysteroscopes and fluid management systems. These are not in the scope of this 510k.

The Interlace Tissue Morcellator System is comprised of the main components as listed below.

- Control Unit
- Reusable Morcellator Handpiece with power cable
- Sterile, Single Use Morcellator blade
- Footswitch

Principles of Operation

The Interlace Medical Hysteroscopic Morcellator is designed for morcellation of intrauterine tissue. The principles of operation are identical to those of the predicate device, the Smith and Nephew Operative Hysteroscopy System.
A disposable straight surgical morcellator is driven by a motorized handpiece and inserted into the uterus via a hysteroscope or access sheath for tissue removal. A footswitch is used to control the power by turning the morcellator on and off. The morcellator consists of a rotating and reciprocating inner tube or cutter whose distal tip is sharpened. The cutter is totally contained within an outer tube and has a fitting at its proximal end to which vacuum tubing is attached. The outer tube incorporates a "cutting window" into which targeted tissue is suctioned, cut, and aspirated through the inner tube to a collection

The Control Unit provides a vacuum monitoring sensor that prohibits morcellation when no vacuum is detected and a timer display that shows morcellation duration.

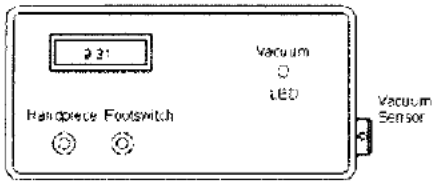
The figures below depict the system components.

Control Unit Front Panel

The control unit front panel includes Morcellation Timer Display, Footswitch and Handpiece Connectors (Figure 1). The Footswitch and Handpiece connectors are located on the front panel. The control unit displays the elapsed morcellation time in MIN:SEC

format. The vacuum LED glows GREEN when vacuum is present and the morcellator interlock allows cutting.

Figure 1. Hysteroscopic Morcellation System Control Unit Front panel.



The control unit has a 3-pronged electrical connector which allows connection of the morcellator system to any 100-120/200-240 VAC, 50/60 Hz, 350 VA source using the power cord supplied with the system. The control unit power supply automatically detects the local power standard and adapts the morcellator system to that standard.

Morcellator Handpiece

The **Morcellator handpiece** is a hand-held motor drive which is electrically connected to the control unit via a 10-foot (3-meter) cable and activated by a footswitch. (b) (4) Trade [redacted]

The ***Suction*** tubing is connected to a stainless steel barbed connector on the proximal end of the handpiece. The suction pressure draws fluid and tissue through the morcellator window. Suction tubing is an off the shelf item in hospitals and is not supplied by Interlace Medical.

Figure 2. Morcellator Handpiece

Single Use Surgical Morcellator

The specifications for the morcellator are identified in the following table

(b)(4) Trade Secret Process - Production Specification

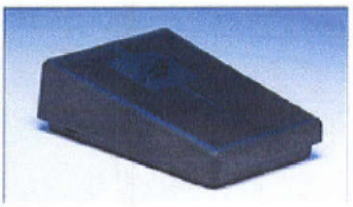
[redacted]

Figure 3. Single Use Surgical Morcellator

Footswitch

The morcellation system Footswitch controls morcellator operation (Figure 4). The footswitch plugs into the connector on the front of the control unit panel. It has single pedal and is pneumatically operated.

Figure 4. Footswitch



Morcellator speed, rotation direction, and oscillation rate are fixed and not able to be modified by the user.

Drawings of the device and system set up are included in Attachment 2.

Section III. Substantial Equivalence

Interlace Medical Hysteroscopic Morcellation System is substantially equivalent to the Smith and Nephew IUR Reciprocating Morcellator cleared under K041774. The following table identifies the similarities and differences between the Interlace Medical Hysteroscopic Morcellation System and its predicate.

SUBSTANTIAL EQUIVALENCE CHART

	Interlace Medical Hysteroscopic Morcellator	Smith & Nephew IUR Reciprocating Morcellator (K041774)
Intended Use	For use in gynecological procedures by trained professional gynecologists to resect and remove endometrial tissue for the following indications, submucous myomas and endometrial polyps.	For use in gynecological procedures by trained professional gynecologists to resect and remove endometrial tissue for the following indications, submucous myomas and endometrial polyps.
Indications for Use	The Interlace Medical hysteroscopic Morcellation System is intended for use in gynecological procedures by trained gynecologists to resect and remove endometrial tissue for the following indications, submucous myomas and endometrial polyps.	The Smith &Nephew IUR Morcellation System is intended for use in gynecological procedures by trained gynecologists to resect and remove endometrial tissue for the following indications, submucous myomas and endometrial polyps.
Morcellator outer diameter	3.0 mm	4.0 mm
Morcellator inner diameter	2.0 mm	3.1 mm
Maximum cutting depth	3.0 mm	4.0 mm
Volume of tissue collected	> 14 cc/ 10 minute (14 cc = 3 cm spherical fibroid)	1 cc/ 10 minute to 5 cc/ 10 min – Schoot BCD, Jaspers J, "Comparison of New Hysteroscopic Shaving Technique to Remove Intrauterine Polyps with Conventional Resection", presented at AAGL Conference , Nov. 2006
Cutting window	13.7 mm x 3 mm = 41 mm^2	10.5 mm x 4 mm = 42 mm^2
Mechanism of action	The morcellator consists of a stationary outer sheath with a cutting window and a rotating and reciprocating inner cutter.	The morcellator consists of a stationary outer sheath with a collection window and a rotating and reciprocating inner cutter.
Mode of operation	Vacuum is used to pull tissue into the cutting window where it is cut and aspirated thru the cutter and deposited into a collection canister.	Vacuum is used to pull tissue into the cutting window where it is cut and aspirated thru the cutter and deposited into a collection canister.

(b)(4) Trade Secret Process - Production Specification

[redacted]

The 510(k) "Substantial equivalence decision making process (detailed) decision tree" (from CDRH 510(k) manual 92-4158) was utilized to make the following determination of substantial equivalence.

1. Does the new device have the same intended use?

Yes, the new device has the same intended use as the predicate, that being for use in gynecological procedures by trained professional gynecologists to resect and remove endometrial tissue for the following indications, submucous myomas and endometrial polyps.

2. Does the new device have the same indication statement as the predicate device?

Yes, the new device has the same indication as the predicate, that being for use in gynecological procedures by trained gynecologists to resect and remove endometrial tissue for the following indications, submucous myomas and endometrial polyps.

3. Does the new device have the same technological characteristics, e.g. design, materials, etc.?

Yes, the design and materials are substantially similar. There are minor differences in dimensional characteristics but these do not raise any new questions of safety and effectiveness since the Interlace Medical Hysteroscopic Morcellation System diameters are smaller than the Smith and Nephew IUR Reciprocating Morcellator.

(b)(4) Trade Secret Process - Production Specification

[redacted]

(b)(4) Trade Secret Process - Production Specification [redacted]

Figure 5

Figure 6

There are several contributing factors to the enhanced performance of the Interlace Morcellator as compared to the predicate: 1) sharper cutting edge, 2) faster rotation speed, 3) faster reciprocation rate, 4) longer window opening and 5) higher vacuum pressure. It is these changes that enable the smaller device to match and exceed the effectiveness of the larger device. These factors do not raise new questions of safety and effectiveness for the following reasons.

1) (b)(4) Trade Secret Process - Production Specification [redacted]

2) (b)(4) Trade Secret Process - Production Specification [redacted]

4. Are descriptive characteristics precise enough to assure equivalence?
Yes, labeling, intended use, and device descriptions ensure equivalence. In addition, bench testing is available to ensure equivalency of the devices.

Statement of Substantial Equivalence

The Interlace System is substantially equivalent in design, materials, construction and intended use as that of the predicate. The principal of operation of both devices are exactly the same. Since the Interlace Morcellator has the same in intended use and technological characteristics as the predicate device, the Interlace Morcellator does not raise any new safety and efficacy concerns when compared to the similar legally marketed device.

The descriptive characteristics demonstrate that the Interlace Morcellator is substantially equivalent to the predicate device and is capable of safely and accurately performing the stated intended use.

Attachment 3 contains information and labeling for the predicate device.

Section IV: Performance Testing

The Interlace Medical Hysteroscopic Morcellation System will be tested and certified to meet the following standards prior to marketing:

- IEC/EN 60601-1: (2004) Medical electrical equipment – Part 1: General requirements for safety.
- IEC/EN 60601-1-1:2000 - Medical electrical equipment. Part 1: General requirements for safety - 1. Collateral standard: Safety requirements for medical electrical systems
- IEC/EN 60601-1-2: 2001 - Medical Electrical Equipment. General Requirements for Safety- Collateral Standard: Electromagnetic Compatibility Requirements and Tests
- IEC/EN 60601-2-18:1996 - Medical electrical equipment -- Part 2: Particular requirements for the safety of endoscopic equipment

(b)(4) Trade Secret Process - Testing

[redacted]

The test protocol and report are included in Attachment 4.

The dimensions of the Interlace Morcellator are such that the compatibility with marketed hysteroscopes is confirmed through engineering analysis and no testing is needed.

(b)(4) Trade Secret Process - Testing

[redacted]

Section V: Sterilization and Biocompatibility

The Interlace Morcellator will be sterilized using ethylene oxide gas by a contract sterilization company per contractually established guidelines. Validation of this method will be accomplished using a protocol consistent with the overkill approach described in the AAMI guideline, ANSI/AAMI/ISO 11135, 1994: *Medical Devices-Validation and routine control of ethylene oxide sterilization.*

The sterility assurance level (SAL) for the proposed device is 10^{-6}.

Maximum residue levels for release purposes of Ethylene Oxide, Ethylene Chlorohydrin, and Ethylene Glycol are maintained in accordance with the proposed rules set forth in the June 23, 1978 Federal Register, Vol 43, No. 122, § 821.100.

Ethylene oxide:	25 ppm
Ethylene chlorohydrin:	250 ppm
Ethylene glycol:	250 ppm

Maximum residue levels for release purposes of Ethylene Oxide, Ethylene Chlorohydrin are maintained in accordance with ISO 10993-7:1995.

Ethylene oxide:	20 mg per device
Ethylene chlorohydrin:	12 mg per device

The packaging in which the Interlace Morcellator will be placed is on a HDPE backing in a standard tyvek/mylar pouch. These materials are routinely used by most manufacturers of single use disposable medical devices. The product will be labeled with an expiration date of two years from the date of sterilization. Interlace will have validated the packaging and sterilization processes prior to marketing.

Biocompatability:

(b)(4) Trade Secret Process - Testing

[redacted]

Section VI: Kit Certification

This device is not part of a kit. This section is not applicable.

Section VII: Software

There is no software in the device. This section is not applicable.

Section VIII: Summary of Safety and Effectiveness

As required by the Safe Medical Devices Act of 1990 and 21 CFR 807.92, a 510K summary is provided in Attachment 5.

Section IX. Attachments

1. Device Labeling
2. Device Drawings
3. Predicate Labeling and Information
4. Performance Data
5. 510K Summary of Safety and Effectiveness

ATTACHMENT 1

Labeling and Instructions for Use

Interlace Medical Disposable Hysteroscopic Morcellator

Instructions for Use

Device Description

Interlace Medical Disposable Hysteroscopic Morcellator is a single use mechanical instrument used exclusively with the Interlace Medical Hysteroscopic Morcellation System for removing tissue.

Indication for Use

The Interlace Medical Disposable Hysteroscopic Morcellator is intended for gynecological procedures by trained gynecologists to resect and remove endometrial tissue for the following indications:

Submucous myomas
Endometrial polyps

Contraindications

Interlace Medical Disposable Hysteroscopic Morcellator is contraindicated for the following conditions:

Pregnancy
Pelvic Infection
Cervical malignancy
Previously diagnosed endometrial cancer

⚠ Warnings

- Contents are sterile unless package is opened or damaged. DO NOT RESTERLIZE. For single use only. Discard any open, unused product. Do not use after the expiration date.
- It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- Read these instructions completely prior to use.
- Periodic irrigation of the morcellator tip is recommended to provide adequate cooling of the morcellator and to prevent accumulation of excised materials in the surgical site. Ensure that suction is flowing while the instrument is running.
- Do not run the morcellator without clear visualization. The morcellator cutting window should be in the field of view at all times while the morcellator is running.
- After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

℞ only Precautions

U.S. Federal law restricts this device to sale by or on the order of a physician.

- Prior to use, inspect the product package for signs of damage or tampering. If damaged, do not use.
- Prior to use, examine the device(s) for possible damage to assure proper functioning. If damaged, do not use.
- Exercise care not to bend the shaft or damage the cutting tip when inserting the morcellator through the hysteroscope working channel.
- Excessive leverage on the morcellator does not improve cutting performance and, in extreme cases, may result in wear and degradation of the inner assembly.
- Discard the device if any component is cracked, worn, broken, or loose.
- Direct contact of the rotating cutting edge of a morcellator with metal (e.g., sheath, hysteroscope, or other instruments) can cause damage to the instrument tip. This damage can range from slight distortion and/or dulling of the cutting edge to actual fracture of the tip. If such contact should occur, stop using the morcellator immediately.

Instructions for use

Note: Refer to the Hysteroscopic Morcellation System Operations Manual (REF 01-001) for detailed instructions for use.

Insertion, Setup, and Removal

For use with Morcellator Handpiece

REF 10-001

1. To insert a morcellator (A), hold handpiece so that you can see retaining ring (B) as shown in Figure 1. Insert the morcellator into the handpiece until it stops on the retaining ring.

2. Guide morcellator (A) into handpiece slot as shown in Figure 2.

3. Slide retaining clip (D) forward until it stops locking the morcellator into position.

4. Slide retaining backward to remove morcellator.

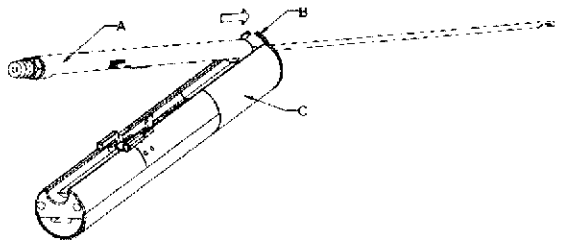


Fig. 1 Insert morcellator (A) into retaining ring (B)

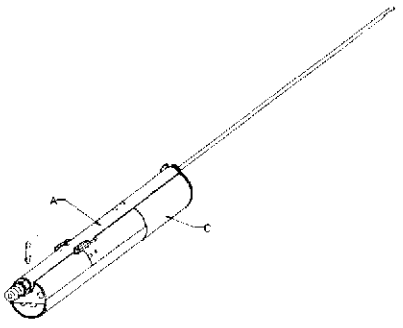


Fig. 2 Drop morcellator (A) into handpiece (C)

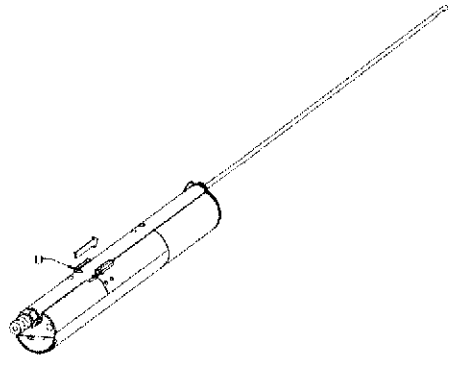


Fig. 3 Slide retaining clip (D) forward to lock morcellator into position

Recommended Parameters

Vacuum pressure > 600mmHg

Warranty

For single use only. This product is warranted to be free from defects in material and workmanship. Do not reuse.

For Further Information

If further information on this product is needed, please contact Interlace Medical at 508-875-1343 in the U.S., or your authorized representative.

Mfd for: Interlace Medical, Inc.
Framingham, MA 01701 USA
508-875-1343

REF 10-

LOT

20XX - XX

20XX - XX

STERILE

Single Use Only

CE

See Instructions

Rx only

EC REP

EU Rep Name Street Address City, Postal Code Country

Hysteroscopic Rotary

02-005 Rev.

Patents

Made in USA

Interlace MEDICAL

REF 10-901

CE XXXX

XXXX-XX

SN XXXXXXX

Patents Pending 02-004 Rev A

MADE IN USA

DO NOT IMMERSE

Interlace™ MEDICAL

REF 10-300

Contents – 1, Control Unit

Read Instructions Prior to Use

℞ only

XXXX-XX

SN XXXXXXX

CE xxxx

EC REP

Manufactured for:
Interlace Medical
139 Newbury Street
Framingham, MA 01701
(508) 875-1343

EU Rep Name
Street Address
City, Postal Code
Country

Patents Pending

02-003 Rev A

Interlace MEDICAL

REF 10-200

Contents – 1, Hysteroscopic Morcellator

Single Use Only

Read Instructions Prior to Use

Rx Only

STERILE EO

XXXX-XX

LOT XXXXXXX

XXXX-XX

CE XXXX

Manufactured for:
Interlace Medical
139 Newbury Street
Framingham, MA 01701
(508) 875-1343

EC REP

EU Rep Name
Street Address
City, Postal Code
Country

Patents Pending

02-002 Rev A

Interlace MEDICAL

REF 10-100

Contents – 1, Handpiece

Read Instructions Prior to Use

Rx only

XXXX-XX

SN XXXXXXX

CE XXXX

Manufactured for:
Interlace Medical
139 Newbury Street
Framingham, MA 01701
(508) 875-1343

EC REP

EU Rep Name
Street Address
City, Postal Code
Country

Patents Pending

02-001 Rev A

Interlace™ MEDICAL

REF 10-300

Hysteroscopic Morcellation Control Unit

SN XXXXXX

100-120/200-240V, 50/60 Hz, XXX VA

CE XXX

Manufactured for:
Interlace Medical
139 Newbury Street
Framingham, MA 01701
(508) 875-1343

EC REP

EU Rep Name
Street Address
City, Postal Code
Country

02-006 Rev. A Patents Pending Made in the USA

Interlace Medical

Hysteroscopic Morcellation System

Preface / Contents / Glossary of Symbols

Preface

This manual provides the information you need to operate and maintain the Interlace Medical Hysteroscopic Morcellation System. It is essential that you read and understand all the information in this manual before using or maintaining the system.

Contents

Introduction, Indications for Use, and Contraindications
Introduction **pg. 2**
Indications for Use **pg. 2**
Contraindications **pg. 2**
Warnings and Precautions
Warnings **pg. 2**
Precautions **pg.3**
Electromagnetic Safety **pg. 3**
System Components
Morcellator Control Unit - Front Panel **pg. 4**
- Timer Display Window **pg. 4**
- Vacuum Light Indicator **pg. 4**
- Morcellator Footswitch and Handpiece Connectors **pg. 4**

Morcellator Control Unit - Rear Panel **pg. 5**
- Power Switch **pg. 5**

Morcellator Handpiece **pg. 5**
Morcellator **pg. 5**
Morcellator Footswitch **pg. 5**
Setup pg. 6
Operation pg. 8
Installing a Morcellator in the Morcellator Handpiece **pg. 8**
Footswitch Operation **pg. 8**
Cleaning
Morcellator Handpiece **pg. 8**
Morcellator Control Unit **pg. 8**
Footswitch **pg. 8**
Maintenance and Service
Electrical Interference **pg. 9**
Environmental Protection **pg. 9**
Preventive Maintenance **pg. 9**
Service Philosophy **pg. 9**
Handpiece Cables **pgs. 10**
Control Unit Fuses **pg. 10**

Troubleshooting pg. 10

Technical Specifications
Morcellator Control Unit **pg. 11**
Morcellator handpiece **pg. 11**
Morcellator Footswitch **pg. 11**
Warranty
New Product Warranty **# 12**
Service Warranty **# 12**
Figures
1) Morcellator Control Unit- Front Panel **# 4**
2) Morcellator Control Unit - Rear Panel **# 5**
3) Morcellator Handpiece **# 5**
4) Morcellator **# 5**
5) Morcellator Footswitch **# 5**
6) System Configuration **# 7**

I ON
Main electrical power on.

O OFF
Main electrical power off.

FOOTSWITCH
Foot pedal Control

CAUTION
See Instructions for use.

EQUIPMENT CLASSIFICATION
Type BF Equipment

REF

CATALOG NUMBER
Part number or reorder number

IPX8

Watertight Equipment
Per IEC 529

138

Introductions, Indications for Use, Contraindications

Introduction

The Interlace Medical Hysteroscopic Morcellation System is designed to meet the requirements of intrauterine morcellation.

A disposable straight surgical morcellator is inserted into a morcellator handpiece for tissue removal requirements. A footswitch allows you to control morcellator action by turning it off and on.

The Interlace Medical Hysteroscopic Morcellation System features many performance and ease-of-use advantages, including:

- A suction monitoring sensor that prohibits morcellation when no vacuum is detected.
- A timer display that shows morcellation duration.

Indications for Use

The Interlace Medical Hysteroscopic Morcellation System is intended for use in gynecological procedures by trained professional gynecologists to resect and remove endometrial tissue for the following indications

- Submucous myomas
- Endometrial polyps

Contraindications

The Interlace Medical Hysteroscopic Morcellation System should not be used with pregnant patients or patients exhibiting pelvic infection, cervical malignancies, or previously diagnosed endometrial cancer.

Warnings and Precautions

Please read this manual before using the Interlace Medical Hysteroscopic Morcellation System. The brief operating instructions in this guide will make the system easier to use, while the recommended maintenance procedures will ensure optimal performance over years of reliable use. Of course, as with any surgical instrument, there are important health and safety considerations. These are listed below and highlighted within the text.

WARNINGS

- Before using the morcellation system for the first time, you should review all available product information. You should be experienced in hysterscopic surgey with powered instruments. Healthy uterine tissue can be injured by improper use of the morcellator. Use every available means to avoid such injury.
- Read these instructions completely prior to use.
- If visualization is lost during any point in the procedure stop cutting immediately.
- Periodic irrigation of the morcellator tip is recommended to provide adequate cooling and to prevent accumulation of excised materials in the surgical site.
- Ensure that vacuum pressure is available before commencing surgery.
- **DANGER**: Risk of explosion if used in the presence of flammable anesthetics.
- If this unit is configured as part of a system, the entire system should be tested for compliance with IEC 60601-1-1.
- If the leakage current of the configured system exceeds the limits of IEC 60601-1-

1, install an appropriately rated UL 2601-1/IEC 60601-1 approved isolation transformer and retest the system.

- The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:
    - Use of the accessory in the patient vicinity.

Precautions

Rx only — U.S. Federal law restricts this device to sale by or on the order of a physician.

- Prior to use, examine the device(s) for possible damage to assure proper functioning. If damaged, do not use.
- Only the Interlace Medical Disposable Morcellator can be used with the Interlace Medical Hysteroscopic Morcellation system. The morcellator is intended for single use only. Do not resterilize. Do not lubricate morcellator. Discard morcellator blade assembly after use.
- Use of reprocessed, single-use morcellator may permanently damage, impede performance, or cause failure of your Interlace Medical Hysteroscopic Morcellator. Use of such products may render any warranties null and void.
- Do not allow the rotating portion of any morcellator to touch any metallic object such as a hysteroscope or sheath. Damage to both instruments is likely. Damage to the morcellator can range from a slight distortion or dulling of the cutting edge to actual fracture of the tip in vivo. If such contact does occur, inspect the tip. If you find cracks, fractures or dulling, or if you have any other reason to suspect a morcellator is damaged, replace it immediately.
- Do not operate the handpiece in the open air for an extended period, as the lack of irrigation may cause the handpiece or a morcellator inserted into the handpiece to overheat and seize.
- Excessive leverage on the morcellator does not improve cutting performance and, in extreme cases, may result in wear and degradation of the inner assembly.
- Do not sterilize or immerse the Morcellator Control Unit in disinfectant.
- Do not cool the morcellator handpiece by immersing it in cold water.
- Electrical safety testing should be performed by a biomedical engineer or other qualified person.
- This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.

Electromagnetic Safety

- The Interlace Medical Hysteroscopic Morcellation System needs special precautions regarding Electromagnet Safety and needs to be installed and put into service according to the Electromagnet Safety information provided in this manual and the Interlace Medical Hysteroscopic Morcellation System Service Manual [Ref. 01-003]
- This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:
    - Reorient or relocate this equipment, the other equipment, or both.
    - Increase the separation between the pieces of equipment.
    - Connect the pieces of equipment into different outlets of circuits.

- Consult a biomedical engineer.

- The following equipment performance is considered safety related performance. That is, the failure or degradation of this performance will pose a safety risk to the patient or operator of this equipment.
  - grounding scheme
  - handpiece operation

- Note: If the Interlace Medical Hysteroscopic Morcellation System is put into service in accordance to the safety instruction in this manual, the product should remain safe and provide the performance listed above. If the product fails to provide this level of performance, the procedure should be aborted and the biomedical staff alerted to the observed problem. The problem needs to be corrected before continuing or starting a new procedure.

- Portable and mobile RF communications equipment, including Cellular Telephones and other wireless devices can affect medical electrical equipment. To insure safe operation of the Interlace Medical Hysteroscopic Morcellation System, do not operate communications equipment or Cellular Telephones at a distance closer than specified in Table XYZ of the Interlace Medical Hysteroscopic Morcellation System's Service Manual [Ref. 01-003].

- The Interlace Medical Hysteroscopic Morcellation System is not designed to work with or in the vicinity of Electrical Surgical Equipment. If Electrical Surgical Equipment must be used in the same area as the Interlace Medical Hysteroscopic Morcellation System, the Interlace Medical Hysteroscopic Morcellation System should be observed for proper operation before performing a procedure. This includes operating the Electrical Surgical Equipment in its active mode at a power level suitable for the procedure.

- For more information regarding the Electromagnetic Safety of this product, please see the Interlace Medical Hysteroscopic Morcellation System Service Manual [Ref. 01-003].

System Components

Morcellator Control Unit

[REF 10-300]

Control Unit - Front Panel

The control unit front panel includes Morcellation Timer Display, Footswitch and Handpiece Connectors (Figure 1)

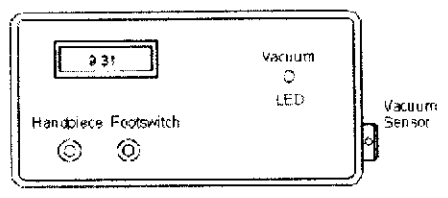


Figure 1 Hysteroscopic Morcellation Control Unit - Front panel

Timer Display Window

The control unit displays the elapsed morcellation time in MIN:SEC format.

Vacuum Light Indicator

The vacuum light indicator will glow GREEN when adequate vacuum is present and RED if it is not. The morcellator handpiece will not run if adequate vacuum is not present.

141

Footswitch and Handpiece Connectors

The Footswitch and Handpiece connectors are located on the front panel.

Control Unit - Rear Panel

There is one connector and a ground terminal on the rear panel (Figure 2).

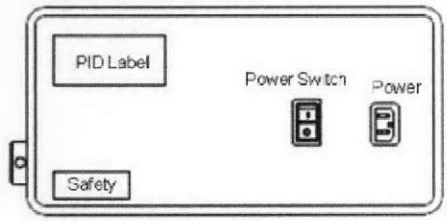


Figure 2 Hysteroscopic Morcellation System Control Unit - Rear panel

Power Switch

The rocker switch near the middle is the power ON / OFF switch for the entire system. The switch is illuminated when the system is ON.

Note: If system is turned off for any reason, wait at least 15 seconds before turning power back on.

The 3-pronged electrical connector allows any 100-120/200-240 VAC, 50/60 Hz, XXX VA source using the power cord supplied with the system. The control unit power supply automatically detects the local power standard and adapts the morcellator to that standard.

The Equipotential Compensator Terminal permits connection of the morcellator control unit to an external earthing system (not shown).

Morcellator Handpiece

[REF 10-100]

The Morcellator handpiece as shown in Figure 3) is a hand-held motor drive which is electrically connected to the control unit via a 10-foot (3-meter) cable and activated by a footswitch as seen in Figure 3.

Figure 3 Morcellator Handpiece

Morcellator

[REF 10-200]

The morcellator is shown in Figure 4. It is a single use device designed to remove intrauterine tissue.

Figure 4 Morcellator

The suction tubing is connected to a stainless steel barbed connector on the proximal end of the morcellator. The suction pressure draws fluid and resected tissue through the morcellator window.

Footswitch

[REF 10-903]

The morcellation system footswitch controls morcellator operation (Figure 5). The footswitch plugs into the connector on the front

of the control unit panel. It has a single pedal and is pneumatically operated.

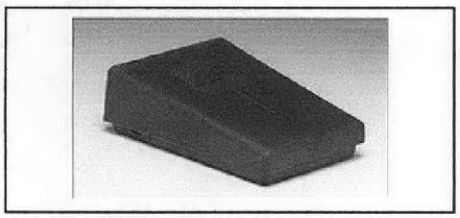


Figure 5. Footswitch

***CAUTION**: Do not operate the handpiece in the open air for an extended period, as the lack of irrigation may cause the handpiece or a morcellator inserted into the handpiece to overheat and seize.*

7. Connect the suction by sliding the suction tubing onto the outflow connector on the proximal end of the morcellator.

Setup

Setting up the Interlace Medical Hysteroscopic Morcellation System

WARNING-DANGER: Risk of explosion if used in the presence of flammable anesthetics

1. Review the System Configuration Diagram in Figure 6 for setup outline.
2. Place the morcellator control unit on top of a cart or other stable work surface. Plug the morcellator control unit power cord into the rear panel connector and a grounded AC power source.
3. Push the power switch on the ON (|) position.
4. Connect the morcellator handpiece cable to the front panel socket. The morcellator handpiece cable connector has a keyed feature that serves to align the handpiece cable to the morcellation control unit connector.
5. Connect the footswitch tube into the connector on the front of the control unit panel.
6. Press the footswitch pedal to confirm handpiece operation.

000043

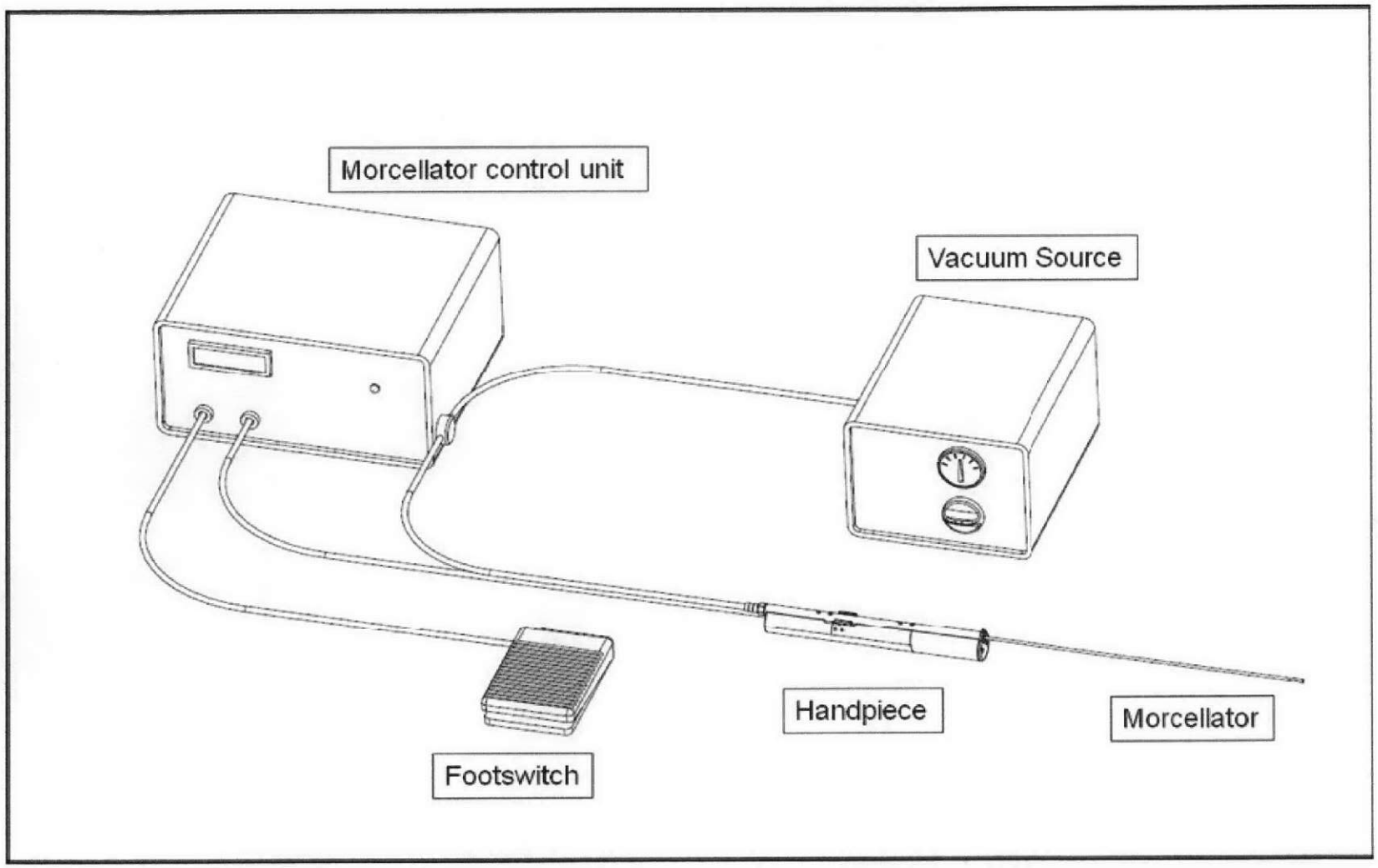


Figure 6. Morcellator Configuration Diagram

Operation

WARNING: Before using the morcellation system for the first time, you should review all available product information. You should be experience in hysteroscopic surgery with powered instruments. Healthly uterine tissue can be injured by improper use of the morcellator. Use every available means to avoid such injury.

1. Verify that the morcellator is sterile.

CAUTION: *Only Interlace Medical Disposable Morcellators can be used with the Interlace Medical Hysteroscopic Morcellation System. The morcellators are intended for single use only. Do not resterilize. Do not lubricate morcellator. Discard morcellator after use.*

Installing a Morcellator in the Morcellator Handpiece

1. Remove the morcellator [REF 10-200] from the sterile package. To insert a morcellator, follow the instructions in the Interlace Medical Disposable Hysteroscopic Morcellator Instructions for Use [REF 01-002].

2. Press the pedal on the footswitch and observe the morcellator action to verify that it is properly installed and operating.

WARNING: Periodic irrigation of the morecellator tip is recommended to provide adequate cooling and to precent accumulation of excised materials in the surgical site.

CAUTION: *Excessive leverage on the morcellator does not improve cutting performance and, inextreme cases, may result in wear and degradation of the inner assembly.*

NOTE: If system is turned off for any reason, wait at least 15 seconds before turning power back on.

Footswitch Operation

The footswitch [REF 10-903] activates morcellator operation. Since the morcellator operates in only one direction and speed, the footswitch merely turns the motor ON and OFF. Once the footswitch is depressed, the morcllator accelerates and rotates to the set speed and continues until the footswitch pedal is released.

Cutting takes place when the morcellator cutting edge rotates and translates across the morcellator's cutting window. The morcellator reciprocating action alternately opens and closes the window to the suction flow.

CLEANING

Morcellator Handpiece, Control Unit and Footswitch Cleaning

Follow this procedure after each operation to clean the control unit and the footswitch:

1. Disconnect the morcellator handpiece from the control unit.

2. Wipe the morcellator with a clean damp cloth and mild germicide or isopropyl alcohol.

3. Disconnect the control unit from the electrical source.

4. Wipe the control unit with a clean damp cloth and mild germicide or isopropyl alcohol.

CAUTION*: Do not sterilize or immerse the Morcellator Control Unit in disinfecant.*

5. Wipe the footswitch and the footswitch tube with a clean damp cloth.

The footswitch [REF 10-903] is watertight per IPX8.

145

Maintenance and Service

Maintenance

Electrical Interference

***Caution**: This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:*

- Reorient or relocate this equipment, the other equipment, or both.
- Increase the separation between the pieces of equipment between the pieces of equipment.
- Connect the pieces of equipment into different outlets or circuits.
- Consult a biomedical engineer.

Environmental Protection

***Caution**: This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.*

Preventative Maintenance

Recommended Annual Performance Checks

Interlace Medical recommends that Dielectric Strength, Earth Leakage Current, and Protective Earth Testing be performed annual to assure continued compliance with applicable safety requirements. These tests should be conducted in accordance with specifications UL 2601-1/IEC 60601-1.

***Caution**: Electrical safety testing should be performed by a biomedical engineer or other qualified person.*

Service

The following are replacement parts for the Interlace Medical Hysteroscopic Morcellation System:

REF	Description
10-900	Control Unit Power Cord
10-901	Handpiece Cable
10-902	Rear Panel Fuse: Replace With x.x amp/250V Quick Acting

Service Philosophy

There are no user serviceable components inside the Hysteroscopic Morcellation System Control Unit and Handpiece. Repairs and adjustments are to be performed only by Interlace Medical authorized service centers.

If service becomes necessary, call your authorized Interlace Medical Customer Service representative prior to returning the device and request a Return Authorization (RA) number. Your representative can also explain the available Service Replacement and Repair Programs.

Service items should be carefully repackaged and returned post-paid to Interlace Medical. Your Interlace Medical customer service representative can provide additional instructions.

Note: Product returned that is found to have been serviced by an unauthorized third party repair facility and/or cleaned with a unapproved biocide other than one approved by Interlace Medical will incur additional costs, regardless of warranty status.

It is not necessary to include accessory items (i.e., power cords, etc.) when returning a device for service.

Morcellator Handpiece Cables

Corrective maintenance involves field replacement of damaged handpiece cables. All other repairs should be performed at the factory or by Interlace Medical authorized service technicians.

1. The morcellator handpiece cable replacement is supplied in a kit with a set of installation instructions. Contact Interlace Medical Customer Service for assistance in obtaining a replacement.

Control Unit Fuses

The control unit is protected by dual x.x amp/250 V fuses mounted on the rear panel below the three-pronged electrical connector, and by a single x.x amp/250V fuse on the power supply board.

If the control unit fails to power up when properly connected to a 100-120/200-240 VAC, 50/60Hz, XXX VA, AC power source, check the fuses in the rear panel.

To change the rear panel fuses:

1. Disconnect the unit from the power source.
2. Locate the fuse tray just above the power cord socket and just below the fuse label (refer to Figure 2 rear panel view).
3. Use a slotted screwdriver to press the tabs on either side of the fuse holder in, toward the center of the tray.
4. Slide the fuse tray out.
5. Replace the fuses with x.x amp/250V Quick Acting fuses [REF 10-902]
6. Insert the tray into the holder until the tabs click into place.
7. Reapply power to the unit.

Note: Blown fuses usually indicate a short circuit or a failed component. Make sure components are properly interconnected. If the problem persists, contact Interlace Medical Customer Service for troubleshooting assistance.

***CAUTION**: Electrical safety testing should be performed by a biomedical engineer or other qualified person.*

Troubleshooting

The Interlace Medical Hysteroscopic Morcellation System is very simple to operate. The unit is switched ON using the rear panel power switch. If the unit does not operate, check the following:

1. Unit is plugged into wall outlet.
2. Wall outlet has power.
3. Power cord is attached to back of control unit.
4. Foot pedal has been connected to front panel.
5. Vacuum pressure is available.
6. Vacuum tubing is connected.

Note: If the system is turned off for any reason, wait at least 15 seconds before turning the power back on.

147

Technical Specifications

Morcellator Control Unit

[REF 10-300]

Dimensions
X wide by Y deep x Z High (XM x YM x ZM)

Weight
TBD Lbs (kg)

Power
100 – 120 / 200 -240 VAC, 50/60 Hz, 350 VA

Equipment Classification
Protection against electrical shock class 1 with BF type applied part. Protection against harmful ingress of water.

Degree of safety of application in the presence of flammable anesthetics with mixture of air, oxygen, or nitrous oxide. (Not suitable)

Mode of Operation
Continuous operation with short-time loading.

Front Panel

Time display window
6-character by one-line numeric display which indicates elapsed time Min:Sec

Connectors
Handpiece cable connetor for handpiece control.

Footswitch cable connector for foot control.

Rear Panel

Power ON/OFF
Illuminated rocker switch

Cooling
None required

AC Power
Detachable power cord with a three-pin hospital-grade connector. Power input circuit automatically detects AC power standard.

Ground Terminal
Equipotential Compensator Terminal

Fuses
Two x.x amp/250 V Quick Acting fuses [REF 10-902]

Morcellator Handpiece [REF 10-100]

Length
TBD

Weight
TBD

Equipped with 10-foot (3-meter) replaceable morcellator handpiece cable.

Morcellator [REF 10-200]

Length
TBD

Weight
TBD

Morcellator Footswitch [REF 10-903]

Dimensions
4" x 6" x 2"

Weight
3.7 lbs

Equipped with 12 foot (3.6 meter) cord. The Footswitch [REF 10-903) is watertight per IPX8.

148

NEW PRODUCT WARRANTY

Interlace Medical products are guaranteed to be free from defects in material and workmanship for one year beginning from date of invoice.

This limited warranty is restricted to repair or replacement by Interlace Medical, at its option, of any product found to be defective during the warranty period. Damage inflicted to a product by the user that causes it to be unsuitable for refurbishment may result in additional charges, regardless of warranty status. All warranties apply to the original buyer only. In no event shall Interlace Medical be liable for any anticipated profits, consequential damages or loss of time incurred by the buyer with the purchase or use of any product.
NO OTHER WARRANTY, EXPRESSED OR IMPLIED, IS GIVEN.

SERVICE WARRANTY

Service Replacement Units Warranty

The Interlace Medical Hysteroscopic Morcellation System replacement unit is warranted to be free from defects in material and workmanship for 90 days from the date of original invoice unless otherwise provided by local law.

Service Replacement Program

Interlace Medical offers a 24-hour Service Replacement Program for its products to minimize downtown in your operating room. Our goal is to ship you a service replacement unit within 24 hours** of your call (during normal business hours). For a Return Authorization (RA) number or for additional information on this program, call Customer Service 1-508-875-1343 in the U.S., or contact your authorized representative.

**24-hour shipment is not offered in all countries

Repair Service Program

For devices no longer under warranty, repairs can be made by Interlace Medical or by an authorized agent. Non-warranty repairs will be made at the list price of replacement parts, plus labor. If requested, we will provide an estimate of repair cost and time required for the repair before any work is done. Repair items should be carefully repackaged, market with the Return Authorization (RA) number, and returned postpaid to the appropriate Interlace Medical Service Center. Interlace Medical Customer Service or your local authorized representative can provide shipping information.

EC	REP

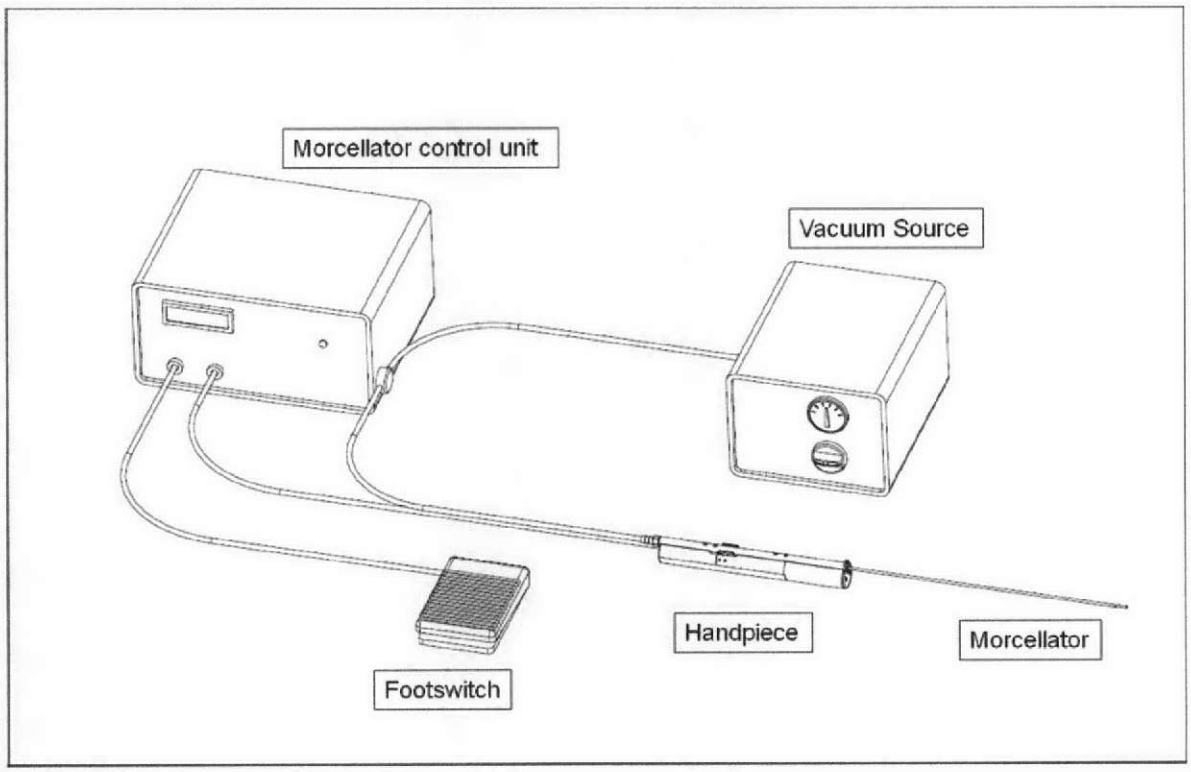
European Representative
Street Address
City, Postal Code
Country

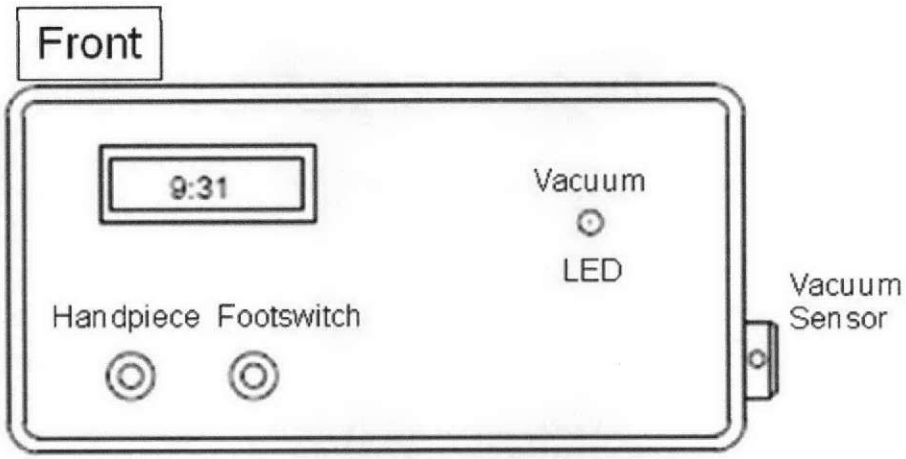
149

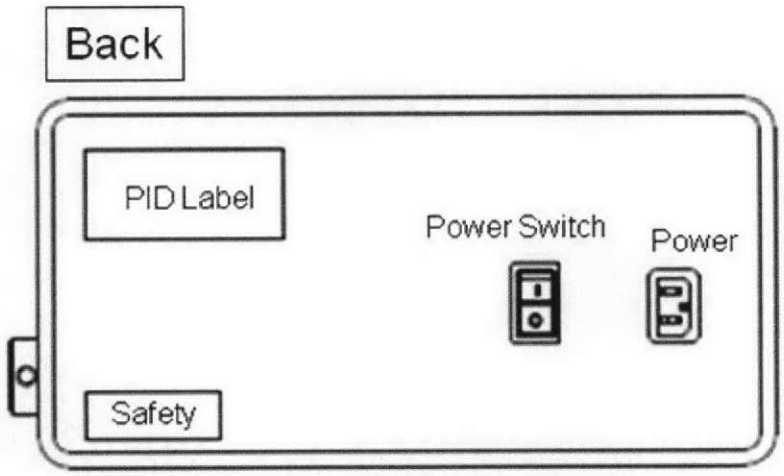
The Interlace Medical Hysteroscopic Morcellation System and components are covered by one or more of the following U. S. Patent Numbers: patents pending

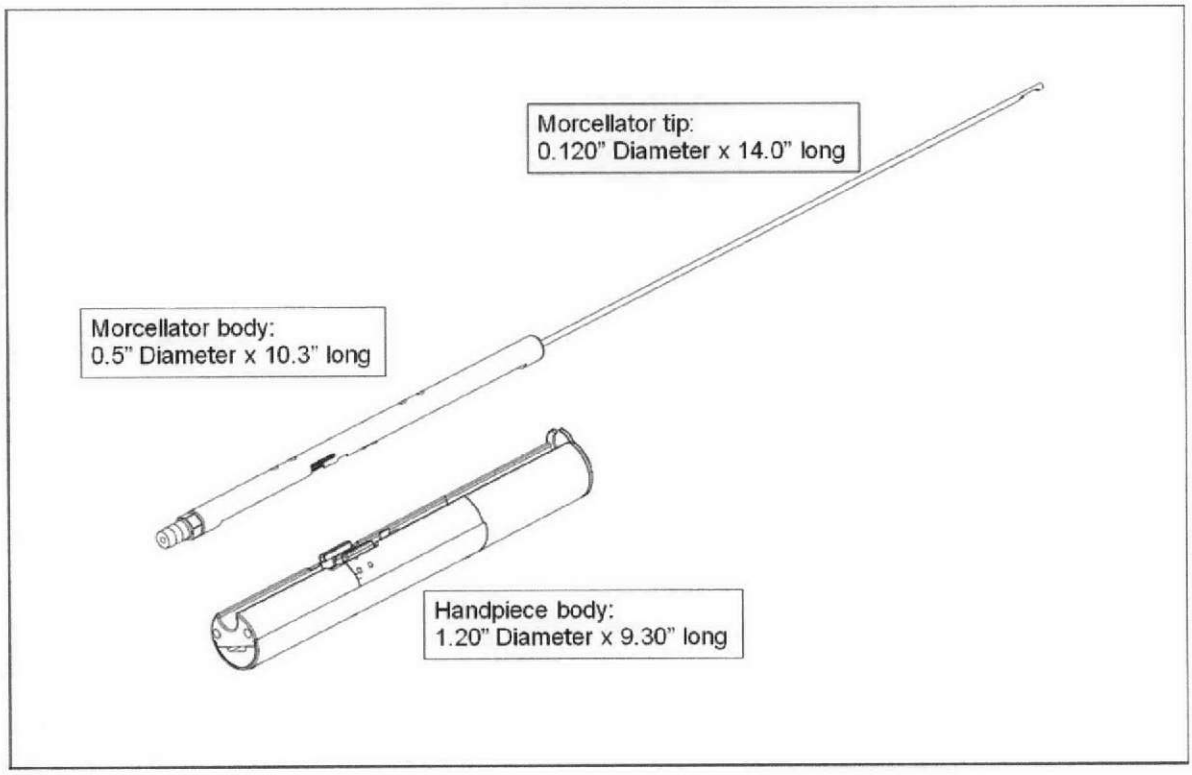
ATTACHMENT 2

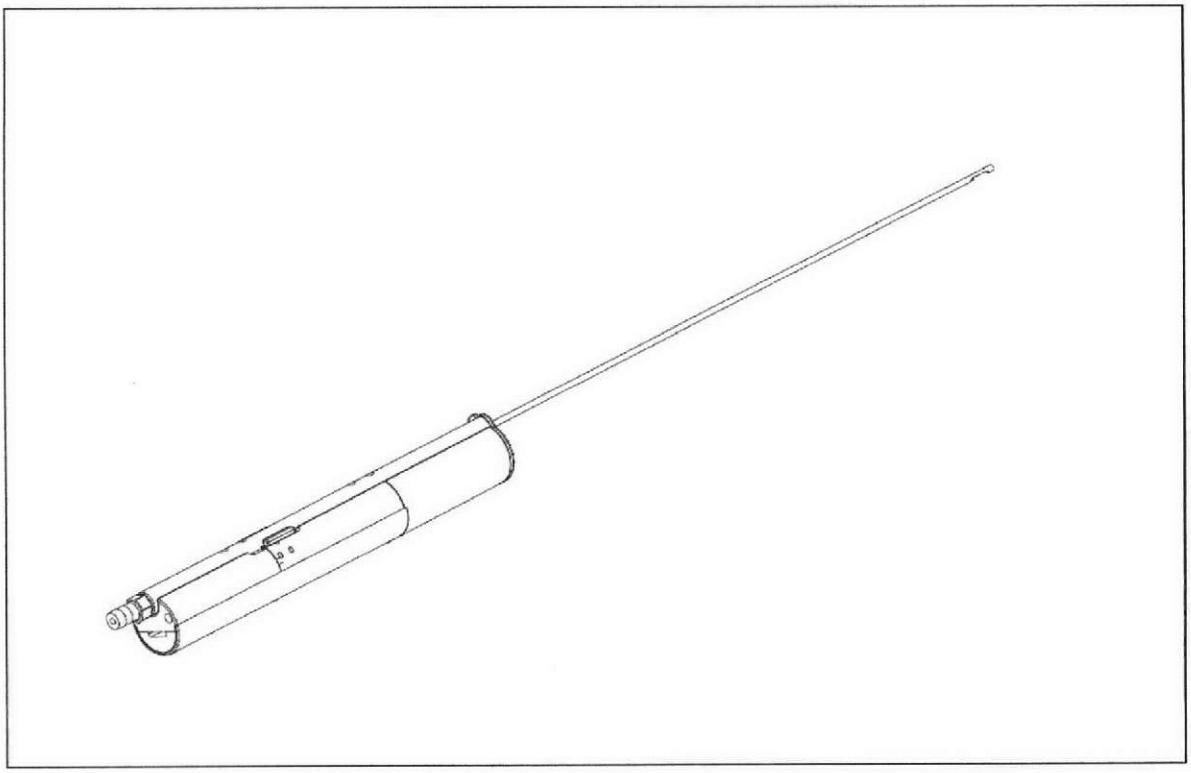
Device Drawings


Morcellator control unit
Vacuum Source
Handpiece
Morcellator
Footswitch


Front
9:31
Vacuum
LED
Vacuum
Sensor
Handpiece
Footswitch


Back
PID Label
Power Switch
Power
Safety


Morcellator tip:
0.120" Diameter x 14.0" long
Morcellator body:
0.5" Diameter x 10.3" long
Handpiece body:
1.20" Diameter x 9.30" long



ATTACHMENT 3

Predicate Device Labeling and Information

K041774
Page 1 of 2

OCT 7 - 2004

SECTION IV

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew IUR Reciprocating Morcellator

Date Prepared: June 30, 2004

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810

B. Company Contact

Janice Haselton
Regulatory Affairs Specialist
Phone: (978) 749-1494
Fax: (978) 749-1443

C. Device Name

Trade Name: Smith & Nephew IUR Reciprocating Morcellator
Common Name: Hysteroscopic Morcellator
Classification Name: Hysteroscopes and Accessories

D. Predicate Devices

The Smith & Nephew Smith & Nephew IUR Reciprocating Morcellator is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution Smith & Nephew IUR Morcellator cleared in K031787.

E. Description of Device

The IUR Reciprocating Morcellator is a disposable, sterile, reciprocating morcellator used in conjunction with the currently cleared Smith & Nephew IUR Morcellation

System (K031787), to remove submucous myomas and endometrial polyps from the uterus. The reciprocating design utilizes both a rotational and reciprocating cutting mechanisms. The predicate design utilizes a rotational cutting mechanism only.

F. Intended Use

The Smith & Nephew IUR Morcellation System is intended for use in gynecological procedures by trained professional gynecologists to resect and remove endometrial tissue for the following indications, submucous myomas and endometrial polyps.

G. Comparison of Technological Characteristics

Both the proposed IUR Reciprocating Morcellator and the predicate IUR Rotary Morcellator, cleared in K031787, are substantially equivalent in intended use, materials and overall design dimensions. Both devices snap and lock in place into the motor drive unit of the IUR Morcellation control unit, via a latch mechanism on the outer adapter body. Based on these similarities Smith & Nephew believes that the IUR Reciprocating Morcellator is substantially equivalent to the predicate device currently on the market.

H. Summary Performance Data

In vitro testing of the IUR Reciprocating Morcellator demonstrates that the addition of new materials and the proposed design modifications does not impact the safety and performance of the proposed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2004

Ms. Janice Haselton
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Endoscopy Division
150 Minuteman Road
ANDOVER MA 01810

Re: K041774
Trade/Device Name: IUR Reciprocating Morcellator
Regulation Number: 21 CFR §884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: 85 HIH
Dated: September 10, 2004
Received: September 13, 2004

Dear Ms. Haselton:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041774

Device Name: _Smith & Nephew IUR Reciprocating Morcellator _____

Indications For Use:

The Smith & Nephew IUR Morcellation System is intended for use in gynecological procedures by trained professional gynocologists to resect and remove endometrial tissue for the following indications, submucous myomas and endometrial polyps.

Prescription Use ___x_____ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041774

Mfd for: Smith & Nephew, Inc.
Andover, MA 01810 U.S.A.

REF 7210908

2007-07

2008-07

LOT 080707

STERILE EO

Single Use Only. Do Not Reuse

CE 0086

See Instructions For Use

Hysteroscopic Reciprocating Morcellator

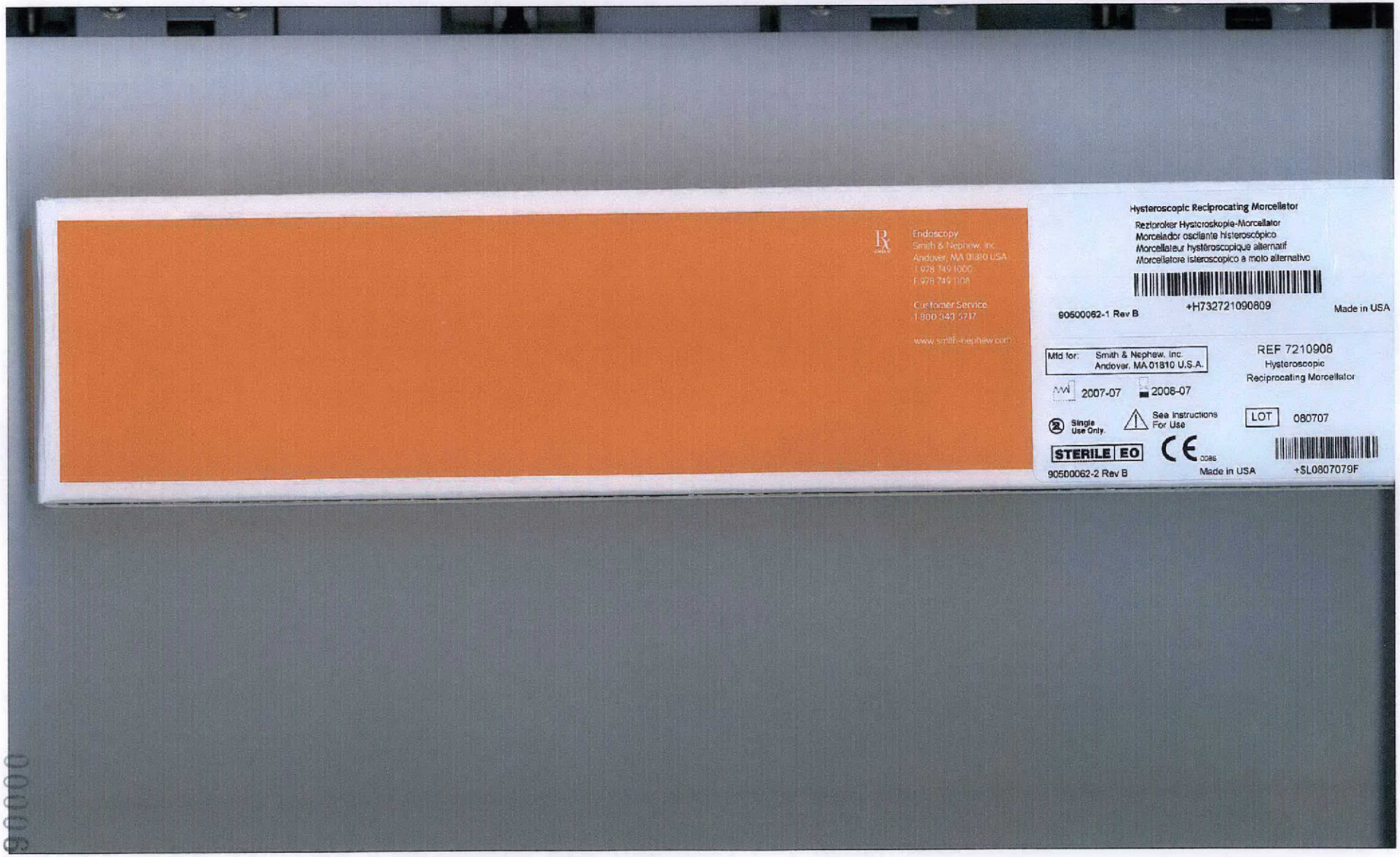
Reziproker Hysteroskopie-Morcellator
Morcelador oscilante histeroscópico
Morcellateur hystéroscopique alternatif
Morcellatore isteroscopico a moto alternativo

90500061 Rev. B

Made in USA

000061

161


Endoscopy
Smith & Nephew, Inc.
Andover, MA 01810 USA
T 978 749 1000
F 978 749 1008
Customer Service
1 800 343 5717
www.smith-nephew.com
Hysteroscopic Reciprocating Morcellator
Reciproker Hysteroskopie-Morcellator
Morcelador osciliante histeroscópico
Morcellateur hystéroscopique alternatif
Morcellatore isteroscopico a moto alternativo
+H732721090809
90500062-1 Rev B
Made in USA
Mfd for: Smith & Nephew, Inc.
Andover, MA 01810 U.S.A.
REF 7210908
Hysteroscopic
Reciprocating Morcellator
2007-07
2008-07
Single Use Only.
See Instructions For Use
LOT 080707
STERILE EO
CE 0086
90500062-2 Rev B
Made in USA
+SL0807079F

000062

Instructions for Use
Gebrauchsanweisung
Modo de empleo
Mode d'emploi
Istruzioni per l'uso
Bruksanvisning
Gebruiksaanwijzing
Bruksanvisning

smith&nephew

Smith & Nephew Disposable Hysteroscopic Morcellators

Einweg-Hysteroskopie-Morcellatoren von Smith & Nephew

Morceladores histeroscópicos desechables de Smith & Nephew

Morcellateurs hystéroscopiques jetables de Smith & Nephew

Morcellatori isteroscopici monouso Smith & Nephew

Smith & Nephew hysteroskopiska morcellatorer för engångsbruk

Smith & Nephew disposable hysteroscopische morcellators

Smith & Nephew hysteroskopiske morcellatorer til engangsbruk

CE 0123

163

Device Description

Smith & Nephew Disposable Hysteroscopic Morcellators are single-use mechanical instruments used exclusively with the Smith & Nephew Hysteroscopic Morcellation System for removing tissue.

Indications for Use

Smith & Nephew Disposable Hysteroscopic Morcellators are intended for gynecological procedures by trained gynecologists to resect and remove endometrial tissue for the following indications:

Submucous myomas

Endometrial polyps

Contraindications

Smith & Nephew Disposable Hysteroscopic Morcellators are contraindicated for the following conditions:

Pregnancy

Pelvic infection

Cervical malignancy

Previously diagnosed endometrial cancer

⚠ Warnings

- **Contents are sterile unless package is opened or damaged. DO NOT RESTERILIZE. For single use only. Discard any open, unused product. Do not use after the expiration date.**
- **It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.**
- **Read these instructions completely prior to use.**
- **Periodic irrigation of the morcellator tip is recommended to provide adequate cooling of the morcellator and to prevent accumulation of excised materials in the surgical site. Ensure that suction of 128 mmHg minimum is flowing while the instrument is running.**
- **Do not run the morcellator without clear visualization. The morcellator cutting window should be in the field of view at all times while the morcellator is running.**
- **It is essential that the *Morcellator Window Lock* feature be set properly to ensure visualization and uterine distention when using the Smith and Nephew Hysteroscopic Morcellation System and Hysteroscopic Fluid Management system.**
- **After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.**

Precautions

℞ U.S. Federal law restricts this device to sale by or on the order of a physician.

- Prior to use, inspect the product package for signs of damage or tampering. If damaged, do not use.
- Prior to use, examine the device(s) for possible damage to assure proper functioning. If damaged, do not use.
- Exercise care not to bend the shaft or damage the cutting tip when inserting the morcellator through the hysteroscope working channel.
- Excessive leverage on the morcellator does not improve cutting performance and, in extreme cases, may result in wear and degradation of the inner assembly.
- Discard the device if any component is cracked, worn, broken, or loose.
- Direct contact of the rotating cutting edge of a morcellator with metal (e.g., sheath, hysteroscope, or other instruments) can cause damage to the instrument tip. This damage can range from slight distortion and/or dulling of the cutting edge to actual fracture of the tip. If such contact should occur, stop using the morcellator immediately.
- Morcellators are supplied as a set and are not interchangeable with other morcellator styles. Do not interchange morcellator components.
- This device SHOULD NOT be used without proper training, preceptorship, and clinical experience.

Instructions for Use

Note: Refer to the Hysteroscopic Morcellation System Operations Manual (REF 1061384) for detailed instructions for use.

To achieve the most efficient cutting performance, Smith & Nephew recommends the use of the Reciprocating Morcellator for the removal of submucosal myomas. The Rotary Morcellator is recommended for the removal of endometrial polyps.

Insertion, Setup, and Removal

For use with Morcellator Handpiece REF 7209807

1. To insert a morcellator, orient the handpiece so that you can see slot (A) on the handpiece and the latch button (B) on the morcellator. Insert the morcellator into the handpiece so that the latch button goes into the slot (Figure 1). The latch button should be pushed in proximally as far as possible for a positive lock.

   Morcellators are marked with a reference line which is centered on the outer cutting window and extends proximally for a distance of 4.5 cm. Markings are provided at .5 cm increments. A corresponding line exists on the inner tube opposite the cutting window for precise window lock alignment.

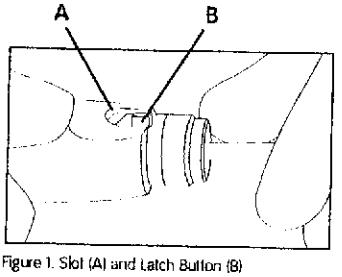


Figure 1. Slot (A) and Latch Button (B)

2. The *Morcellator Window Lock* feature on the morcellator needs to be set prior to use to ensure proper control of fluid flow. To set the Window Lock feature, the axial reference lines on both the inner and outer tubes must be aligned. Depress the Window Lock button on the morcellation system control unit footswitch to slowly rotate the inner tube until the axial lines on both tubes are aligned.
3. To remove a morcellator, depress the latch button on the morcellator with your thumb or fingertip. This will disengage the morcellator hub from the handpiece. Withdraw the morcellator from the handpiece.

Recommended Parameters

Rotary Morcellator - 750 rpm in oscillate mode

Reciprocating Morcellator – 1100 RPM in forward or reverse mode

Warranty

For single use only. This product is warranted to be free from defects in material and workmanship. Do not reuse.

For Further Information

If further information on this product is needed, please contact Smith & Nephew Customer Service at 1-800-343-5717 in the U.S., or your authorized representative.

ATTACHMENT 4

Performance Data

Equivalency Testing Summary

(b)(4) Trade Secret Process - Testing

[redacted]

I. Introduction & Background

(b)(4) Trade Secret Process - Testing

[redacted]

II. Results

(b)(4) Trade Secret Process - Testing

[redacted]

CONFIDENTIAL

Figure 1.

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

[redacted]

CONFIDENTIAL

Figure 2.

(b)(4) Trade Secret Process - Testing

[redacted]

000068

CONFIDENTIAL

168

(b)(4) Trade Secret Process - Testing

[redacted]

Appendix A

CONFIDENTIAL

Appendix B

Protocol Outline

(b)(4) Trade Secret Process - Testing

[redacted]

III. Abstract

(b)(4) Trade Secret Process - Testing

[redacted]

IV. Background and Significance/Preliminary Studies

(b)(4) Trade Secret Process - Testing

[redacted]

000070

CONFIDENTIAL

170

(b)(4) Trade Secret Process - Preliminary StudiesTesting

[redacted]

CONFIDENTIAL

(b)(4) Trade Secret Process - Preliminary StudiesTesting

[redacted]

000072

CONFIDENTIAL

(b)(4) Trade Secret Process - Preliminary StudiesTesting

[redacted]

CONFIDENTIAL

(b)(4) Trade Secret Process - Preliminary StudiesTesting

[redacted]

CONFIDENTIAL

V. Study Aims

(b)(4) Trade Secret Process - Preliminary StudiesTesting

[redacted]

VI. Administrative Organization

(b)(4) Trade Secret Process - Preliminary StudiesTesting

[redacted]

VII. Study Design

(b)(4) Trade Secret Process - Preliminary StudiesTesting

[redacted]

CONFIDENTIAL

(b)(4) Trade Secret Process - Preliminary StudiesTesting

[redacted]

VIII. Study Procedures

(b)(4) Trade Secret Process - Preliminary StudiesTesting

[redacted]

(b)(4) Trade Secret Process - Preliminary StudiesTesting

[redacted]

CONFIDENTIAL

Test Date: _____

Test Data Table:

[redacted]

(b)(4) Trade Secret Process - Preliminary StudiesTesting

CONFIDENTIAL

IX. Analysis Plan

(b)(4) Trade Secret Process - Preliminary StudiesTesting

[redacted]

X. Literature Cited

(b)(4) Trade Secret Process - Preliminary StudiesTesting

[redacted]

CONFIDENTIAL

ATTACHMENT 5

510K Summary of Safety and Effectiveness

Interlace Medical
Hysteroscopic Morcellation System
510K Summary of Safety and Effectiveness
December 28, 2007

1. Sponsor Name
   Sponsor/Manufacturer
   Interlace Medical Inc.
   139 Newbury St
   Framingham, MA 01701
   Telephone: 508.875.1343

2. Device Name
   Proprietary Name: Interlace Medical Hysteroscopic Morcellation System
   Common/Usual Name: Hysteroscope and accessories

3. Identification of Predicate or Legally Marketed Device
   The Interlace Medical Hysteroscopic Morcellation System is substantially equivalent to the Smith and Nephew Hysteroscopic Morcellation System K041774.

4. Device Description
   The system consists of the following components:

   - Control Unit
   - Morcellator Handpiece
   - Single Use Morcellator
   - Footswitch

   The Interlace Medical Hysteroscopic Morcellation System will be used with standard hysteroscopes and fluid management systems.

5. Intended Use
   The Interlace Medical Hysteroscopic Morcellation System is intended for use in gynecological procedures to resect and remove endometrial tissue for the following indications: Submucous myomas, Endometrial polyps.

6. Comparison of Technological Characteristics
   The principles of operation of the Interlace Medical Hysteroscopic Morcellation System are identical to those of the predicate device, the Smith and Nephew Hysteroscopic Morcellation System K041774. A disposable straight surgical morcellator is inserted into a morcellator handpiece for tissue removal. A footswitch is used to turn the morcellator on and off. The morcellator consists of a

rotating and reciprocating inner tube or cutter that is totally contained within an outer tube and has a fitting at its proximal end to which vacuum tubing is attached. The outer tube incorporates a "cutting window" through which targeted tissue is pulled, cut, and moved back through the inner tube to a collection canister.

7 Performance Testing

The Interlace Medical Hysteroscopic Morcellation System meets electrical safety and EMC standards. In addition, an in-vitro test was conducted which demonstrated that the device performs equivalent to or better than the predicate device.

8. Statement of Equivalency

The Interlace System is substantially equivalent in design, materials, construction and intended use as that of the predicate. The principal of operation of both devices are exactly the same. Since the Interlace Morcellator has the same in intended use and technological characteristics as the predicate device, the Interlace Morcellator does not raise any new safety and efficacy concerns when compared to the similar legally marketed device.

The descriptive characteristics demonstrate that the Interlace Morcellator is substantially equivalent to the predicate device and is capable of safely and accurately performing the stated intended use.

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

COVER SHEET MEMORANDUM

From: Reviewer Name VERONICA PRICE

Subject: 510(k) Number K073690/S

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☐ Hold (Additional Information or Telephone Hold).

☑ Final Decision (SE) SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			✓
Is this a combination product? (Please specify category ✓, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Is clinical data necessary to support the review of this 510(k)?			✓
Does this device include an Animal Tissue Source?			✓
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		✓

Regulation Number	Class*	Product Code
884.1690	II	HIH

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Colin M Pollard (Branch Chief) OGDB (Branch Code) 4/10/08 (Date)

Final Review: [signature] (Division Director) 4/17/08 (Date)

Rev. 5/30/07

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

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

Premarket Notification [510(k)] Review
Traditional

K073690/S1

Date:	April 9, 2008	
To:	The Record	Office: ODE
From:	Veronica Price Biomedical Engineer, OGDB	Division: DRARD
510(k) Holder:	Interlace Medical, Inc.	
Device Name:	Interlace Medical Hysteroscopic Morcellation System	
Contact:	Ron Adams CTO 139 Newbury Street Framingham, MA 01701 Phone: 508-875-1343 Fax: 508-370-8026 Email: ron@interlacemedical.com	
Predicate:	Smith and Nephew IUR Reciprocating Morcellator (K041774)	

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the Interlace Medical Hysteroscopic Morcellation System into interstate commerce. An in-depth review of the original 510(k) identified deficiencies. The file was placed on hold based on the additional deficiencies identified in a March 5, 2008, e-mail to the manufacturer. Supplement 1 has been submitted to address these deficiencies.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	√		
Truthful and Accuracy Statement	√		
510(k) Summary or 510(k) Statement	√		
Standards Form			√

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		√	
Is the device an implant (implanted longer than 30 days)?		√	

5

	Yes	No	N/A
Does the device design use software?		√	
Is the device sterile?	√*		
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	√**		

The Interlace Morcellator System is a multiple-use device intended for morcellation and removal of tissue under hysteroscopic visualization. The Interlace Morcellator System will be used with standard hysteroscopes and fluid management systems. The system consists of the following components:

- Control Unit
- *Reusable Morcellator Handpiece with power cable
- **Sterile, Single Use Morcellator
- Footswitch

Control Unit
The control unit front panel includes Morcellation Time Display, Footswitch and Handpiece Connectors and a vacuum LED. The control unit provides a vacuum monitoring sensor which is a flow switch that detects flow. If flow is present, the switch is closed enabling the morcellator motors to run and the LED is changed from Red to Green. The control unit also includes a timer display that shows morcellation duration. The control unit allows connection of the system to any 100-120/200-240 VAC, 50/60 Hz, 350 VA source using the power cord supplied with the system.

Morcellator Handpiece
(b)(4) Trade Secret Process - Product Specification
[redacted]

Morcellator
(b)(4) Trade Secret Process - Product Specification
[redacted]

Footswitch
The footswitch controls morcellator operation.

Principle of Operation:

The disposable straight surgical morcellator is inserted into the uterus via a hysteroscope or access sheath for tissue removal. A footswitch is used to control the power to the motorized handpiece which operates the morcellator. Targeted tissue is placed adjacent to the "cutting window." The tissue is suctioned, cut, and aspirated through the inner tube to a collection canister. Morcellator speed, rotation direction and oscillation rate are fixed and not able to be modified by the user.

IV. Indications for Use

The Interlace Medical Hysteroscopic Morcellation System is intended for use in gynecological procedures by trained gynecologists to resect and remove endometrial tissue for the following indications: submucous myomas and endometrial polyps.

V. Predicate Device Comparison

The manufacturer has identified the Smith & Nephew IUR Reciprocating Morcellator, K041774, as the predicate.

	Interlace Medical Hysteroscopic Morcellator	Smith & Nephew IUR Reciprocating Morcellator K041774
Indication for Use	For use in gynecological procedures by trained gynecologists to resect and remove endometrial tissue for the following indications: submucous myomas and endometrial polyps.	Same
Mechanism of action	The morcellator consists of a stationary outer sheath with a cutting window and a rotating and reciprocating inner cutter	Same
Mode of operation	Vacuum is used to pull tissue into the cutting window where it is cut and aspirated thru the cutter and deposited into a collection canister	Same
Morcellator Outer Diameter	3.0 mm	4.0 mm
Morcellator Inner Diameter	2.0 mm	3.1 mm
Maximum Cutting Depth	3.0 mm	4.0 mm
Cutting Window	13.7 mm x 3 mm (41 mm^2)	10.5 mm x 4 mm (42 mm^2)
Reciprocation rate	2.8 cycles/sec	2.6 cycles/sec
Rotation rate	6000 rpm	1100 rpm
Aspiration vacuum pressure	600-650 mmHg	≤200 mmHg
Cutting tip configuration	Smooth circular edge	Same

(b)(4) Trade Secret Process - Product Specification

[redacted]

The following concern was raised regarding the difference in rotation rate between the two devices:

(b)(4) Trade Secret Process - Product Specification

[redacted]

7

(b)(4) Trade Secret Process - Product Specification

[redacted]

VI. Labeling (Attachment 1)

The manufacturer has provided Instructions for Use for the Interlace Medical Disposable Hysteroscopic Morcellator and an Operating Manual for the Interlace Medical Hysteroscopic Morcellation System. The manufacturer has also provided copies of the package labels. A number of changes to the labeling were requested in the 2/27 e-mail. The requested changes and the manufacturer's responses are outlined below:

- *In the Device Description you have indicated that the morcellator handpiece is covered with a protective sterile drape. This is presumably and "off the shelf" item. This information should be included in the Interlace Medical Hysteroscopic Morcellation System Operating Manual.*

(b)(4) Trade Secret Process - Product Specification

[redacted]

- (b)(4) Trade Secret Process - Product Specification

  [redacted]

- (b)(4) Trade Secret Process - Product Specification

  [redacted]

VII. Sterilization/Shelf Life/Reuse

The morcellator (blade) is a single, use component of the System. The following sterilization information has been provided:

1. Sterilant: Ethylene Oxide	YES	NO
a. **Sterilization method** description	EtO	
b. **Dose**, for radiation	n/a	
c. **Sterilant residuals** remaining on the device:	ethylene oxide: 20 mg/per device ethylene chlorohydrin: 12 mg/per device	
2. A description of the Validation Method for the sterilization cycle (not data):	Overkill method as per ANSI/AAMI/ISO 11135	
3. Sterility assurance level (SAL):	10^{-6}	
4. Is it labeled "Pyrogen Free"?		√
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))		
5. A description of the packaging (not including package integrity test data):	HDPE backing in standard Tyvek/mylar pouch	

The morcellator is labeled with a 2-year shelf life.

VIII. Biocompatibility

(b)(4) Trade Secret Process - Testing

[redacted]

IX. Software- N/A

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The manufacturer has indicated that the following testing ***will be*** conducted on the Interlace Morcellator:

- IEC 60601-1:1998 + A1:1991 + A2:1995 Medical electrical equipment- Part 1: General requirements for safety
- IEC 60601-1-2 (2001) Medical electrical equipment- Part 1: General requirements for safety- Collateral Standard; Electromagnetic Compatibility – Requirements and Tests
- IEC/EN 60601-2-18: 1996 + A1:2000 – Medical electrical equipment – Part 2: Particular requirements for the safety of endoscopic equipment

The following deficiency regarding these tests was included in the 2/27/08 e-mail:

In Section IV Performance Testing, you have indicated that electrical safety and electromagnetic safety testing will be conducted on the Interlace Medical Hysteroscopic Morcellation System prior to marketing. Before a determination of substantial equivalence can be made, this testing will need to be conducted and certification that the referenced standards have been met provided. Please

provide this information for review.

The manufacturer has provided a summary of the test plans that will be used to demonstrate that the requirements of the listed recognized standards pertaining to electrical safety and EMC will be met prior to commercialization. Although a certification that the testing was conducted and passed was requested, this alternative proposal is acceptable. This is based on the guidance provided to Industry and FDA Staff in the guidance entitled, "Use of Standards in Substantial Equivalence Determinations" dated March 12, 2000.

XI. Performance Testing – Bench

(b)(4) Trade Secret Process - Testing

[redacted]

- (b)(4) Trade Secret Process - Testing

  [redacted]

- (b)(4) Trade Secret Process - Testing

  [redacted]

- (b)(4) Trade Secret Process - Testing

  [redacted]

10

(b)(4) Trade Secret Process - Testing

[redacted]

XII. Performance Testing – Animal

None provided.

XIII. Performance Testing – Clinical

None provided.

XIV. Substantial Equivalence Discussion

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

5. Explain how descriptive characteristics are not precise enough:
The manufacturer needs to provide the results of testing that demonstrates substantial equivalence with respect to the performance of the Interlace Hysteroscopic Morcellation System when compared to the predicate given the differences in rotational speed, suction pressure, etc.

11

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

(b)(4) Trade Secret Process - Testing

[redacted]

XV. Deficiencies

The manufacturer was sent an e-mail on March 5th requesting the following additional information:

1. (b)(4) Trade Secret Process - Testing

[redacted]

12

(b)(4) Trade Secret Process - Testing

[redacted]

2. [redacted]

3. [redacted]

XVI. **Contact History**

2/27/08	FDA e-mail with deficiencies
2/29/08	Teleconference with Ron Adams to clarify some deficiencies
3/3/08	Manufacturers e-mail responses
3/5/08	FDA e-mail with remaining deficiencies/Notification of Hold Status
3/7/08	Teleconference with Ron Adams to clarify deficiencies

XVII. Recommendation

Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: Class II
Product Code: HIH

Veronica A Pina — 4/9/08
Reviewer — Date

Colin M Pollard — 4/10/08
Branch Chief — Date

Pollard, Colin M.

From: Pollard, Colin M.
Sent: Thursday, April 10, 2008 2:46 PM
To: Price, Veronica A.
Subject: K073690, Hysteroscopic Morcellation System

Veronica:

I was about to send Mr. Adams the following e-mail and then remembered that you like to do this yourself!

-- Colin

Mr. Adams:

I am looking over your 510(k) premarket notification, including Ms. Price's review memo and SE recommendation.

Could you please send me a revised *Indications for Use* (IFU stmt), to read as follows:

> *The Interlace Medical Hysteroscopic Morcellation System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue from submucous myomas and endometrial polyps.*

The changes include:

- Replacing "gynecological procedures" with "hysteroscopic intrauterine procedures". ("Gynecological" is too general)
- Incorporating "submucous myomas" and "endometrial polyps" into the sentence, and deleting "indications". Those are *types* of tissue, not really indications.

Please get back to me as soon as possible. Please send a revised IFU stmt, per our standard format.

Thank you.

Colin Pollard
Chief, Ob/Gyn Devices Branch
DRARD/Office of Device Evaluation
Center for Devices & Radiological Health (FDA)

15

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

COVER SHEET MEMORANDUM

From: Reviewer Name VERONICA PRICE

Subject: 510(k) Number K073690

To: The Record

Please list CTS decision code TH

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☑ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)		✓	
Is this a combination product? N (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Is clinical data necessary to support the review of this 510(k)?			✓
Does this device include an Animal Tissue Source?			✓
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		✓

Regulation Number	Class*	Product Code
884.1690	II	HIH (accessory)

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: Kathryn J. Dawe-Kopp (Branch Chief) for C. Pollard — OGDB (Branch Code) — 3/6/08 (Date)

Final Review: _____ (Division Director) (Date)

Rev. 5/30/07

Price, Veronica A.

From: Price, Veronica A.
Sent: Wednesday, March 05, 2008 6:21 PM
To: 'Ron Adams'
Cc: Price, Veronica A.; Pollard, Colin M.
Subject: K073690 Interlace Hysteroscopic Morcellation System

Dear Mr. Adams,

I have completed my in-depth review of this 510(k) which included a review of your March 3rd responses to my February 27th request for additional information. I have identified the following outstanding items that need to be addressed:

1. (b)(4) Trade Secret Process - Testing [redacted]
2. (b)(4) Trade Secret Process - Testing [redacted]
3. (b)(4) Trade Secret Process - Testing [redacted]

Based on the need for additional testing, I am placing the file on hold. Once you have obtained the necessary information to address the deficiencies identified above, please submit a formal supplement to the 510(k) via the Document Mail Center. Once the formal supplement has been received, I will resume my review of this file. If you require any clarification, please feel free to contact me by e-mail (Thursday/Monday) or by phone.

Sincerely,

Veronica Price
Biomedical Engineer
Obstetrics & Gynecology Devices Branch
FDA
(240) 276-4174
fax: (240) 276-4156
e-mail: veronica.price@fda.hhs.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

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

Premarket Notification [510(k)] Review
Traditional

K073690

Date:	March 5, 2008	
To:	The Record	Office: ODE
From:	Veronica Price Biomedical Engineer, OGDB	Division: DRARD
510(k) Holder:	Interlace Medical, Inc.	
Device Name:	Interlace Medical Hysteroscopic Morcellation System	
Contact:	Ron Adams CTO 139 Newbury Street Framingham, MA 01701 Phone: 508-875-1343 Fax: 508-370-8026 Email: ron@interlacemedical.com	
Predicate:	Smith and Nephew IUR Reciprocating Morcellator (K041774)	

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the Interlace Medical Hysteroscopic Morcellation System into interstate commerce.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	√		
Truthful and Accuracy Statement	√		
510(k) Summary or 510(k) Statement			
Standards Form			

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		√	
Is the device an implant (implanted longer than 30 days)?		√	
Does the device design use software?		√	

40

	Yes	No	N/A
Is the device sterile?	√*		
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	√**		

The Interlace Morcellator System is a multiple-use device intended for morcellation and removal of tissue under hysteroscopic visualization. The Interlace Morcellator System will be used with standard hysteroscopes and fluid management systems. The system consists of the following components:

- Control Unit
- *Reusable Morcellator Handpiece with power cable
- **Sterile, Single Use Morcellator
- Footswitch

Control Unit
The control unit front panel includes Morcellation Time Display, Footswitch and Handpiece Connectors and a vacuum LED. The control unit provides a vacuum monitoring sensor which is a flow switch that detects flow. If flow is present, the switch is closed enabling the morcellator motors to run and the LED is changed from Red to Green. The control unit also includes a timer display that shows morcellation duration. The control unit allows connection of the system to any 100-120/200-240 VAC, 50/60 Hz, 350 VA source using the power cord supplied with the system.

Morcellator Handpiece
(b)(4) Trade Secret Process - Product Specification
[redacted]

Morcellator
(b)(4) Trade Secret Process - Product Specification
[redacted]

Footswitch
The footswitch controls morcellator operation.

Principle of Operation:

(b)(4) Trade Secret Process - Product Specification
[redacted]

IV. Indications for Use

The Interlace Medical Hysteroscopic Morcellation System is intended for use in gynecological procedures by trained gynecologists to resect and remove endometrial tissue for the following indications: submucous myomas and endometrial polyps.

V. Predicate Device Comparison

The manufacturer has identified the Smith & Nephew IUR Reciprocating Morcellator, K041774, as the

predicate.

	Interlace Medical Hysteroscopic Morcellator	Smith & Nephew IUR Reciprocating Morcellator K041774
Indication for Use	For use in gynecological procedures by trained gynecologists to resect and remove endometrial tissue for the following indications: submucous myomas and endometrial polyps.	Same
Mechanism of action	The morcellator consists of a stationary outer sheath with a cutting window and a rotating and reciprocating inner cutter	Same
Mode of operation	Vacuum is used to pull tissue into the cutting window where it is cut and aspirated thru the cutter and deposited into a collection canister	Same
Morcellator Outer Diameter	3.0 mm	4.0 mm
Morcellator Inner Diameter	2.0 mm	3.1 mm
Maximum Cutting Depth	3.0 mm	4.0 mm
Cutting Window	13.7 mm x 3 mm (41 mm^2)	10.5 mm x 4 mm (42 mm^2)
Reciprocation rate	2.8 cycles/sec	2.6 cycles/sec
Rotation rate	6000 rpm	1100 rpm
Aspiration vacuum pressure	600-650 mmHg	≤200 mmHg
Cutting tip configuration	Smooth circular edge	Same

(b)(4) Trade Secret Process - Product Specification

[redacted]

The following concern was raised regarding the difference in rotation rate between the two devices:

(b)(4) Trade Secret Process - Product Specification

[redacted]

48

VI. Labeling (Attachment 1)

The manufacturer has provided Instructions for Use for the Interlace Medical Disposable Hysteroscopic Morcellator and an Operating Manual for the Interlace Medical Hysteroscopic Morcellation System. The manufacturer has also provided copies of the package labels. A number of changes to the labeling were requested in the 2/27 e-mail. The requested changes and the manufacturer's responses are outlined below:

- (b)(4) Trade Secret Process - Product Specification [redacted]
- (b)(4) Trade Secret Process - Product Specification [redacted]
- (b)(4) Trade Secret Process - Product Specification [redacted]

VII. Sterilization/Shelf Life/Reuse

The morcellator (blade) is a single, use component of the System. The following sterilization information has been provided:

1. Sterilant: Ethylene Oxide	YES	NO
a. **Sterilization method** description	EtO	
b. **Dose**, for radiation	n/a	
c. **Sterilant residuals** remaining on the device:	ethylene oxide: 20 mg/per device ethylene	

49

	chlorohydrin: 12 mg/per device	
2. A description of the Validation Method for the sterilization cycle (not data):	Overkill method as per ANSI/AAMI/ISO 11135	
3. Sterility assurance level (SAL):	10^{-6}	
4. Is it labeled "Pyrogen Free"?		√
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))		
5. A description of the packaging (not including package integrity test data):	HDPE backing in standard Tyvek/mylar pouch	

The morcellator is labeled with a 2-year shelf life.

VIII. Biocompatibility

(b)(4) Trade Secret Process - Testing

[redacted]

IX. Software- N/A

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The manufacturer has indicated that the following testing ***will be*** conducted on the Interlace Morcellator:

- IEC 60601-1:1998 + A1:1991 + A2:1995 Medical electrical equipment- Part 1: General requirements for safety
- IEC 60601-1-2 (2001) Medical electrical equipment- Part 1: General requirements for safety- Collateral Standard; Electromagnetic Compatibility – Requirements and Tests
- IEC/EN 60601-2-18: 1996 + A1:2000 – Medical electrical equipment – Part 2: Particular requirements for the safety of endoscopic equipment

The following deficiency regarding these tests was included in the 2/27/08 e-mail:

In Section IV Performance Testing, you have indicated that electrical safety and electromagnetic safety testing will be conducted on the Interlace Medical Hysteroscopic Morcellation System prior to marketing. Before a determination of substantial equivalence can be made, this testing will need to be conducted and certification that the referenced standards have been met provided. Please provide this information for review.

The manufacturer has provided a summary of the test plans that will be used to demonstrate that the requirements of the listed recognized standards pertaining to electrical safety and EMC will be met prior to commercialization. Although a certification that the testing was conducted and passed was requested, this alternative proposal is acceptable. This is based on the guidance provided to Industry and FDA Staff in the guidance entitled, "Use of Standards in Substantial Equivalence Determinations" dated March 12, 2000. The following excerpt:

50

B. Use of FDA-Recognized Standards Without a Declaration of Conformity

Manufacturers may include a statement in a 510(k) that a device conforms (or will conform before marketing) to an FDA-recognized standard, without submitting a declaration of conformity. This is the pre-FDAMA approach discussed earlier in this memorandum, except that the approach is strengthened by the use of an FDA-recognized standard. FDA's recognition signifies that FDA is familiar with the standard and believes it can be used to meet 510(k) requirements, to the extent addressed by the standard. ODE's basis for relying on the statement is the same as it was before enactment of Section 514(c).

ODE reviewers should follow essentially the same review procedures for 510(k)s containing statements as for 510(k)s containing a declaration of conformity. In particular, reviewers should routinely accept a statement about conformity with an FDA-recognized standard to meet relevant 510(k) requirements and not require the submission of information demonstrating conformity with the standard. (Manufacturers must have information demonstrating conformity before they market the device, and these records will be subject to FDA inspection under a compliance program to assess conformance to the quality systems regulation.) While the 510(k) will not contain a declaration of conformity, reviewers should ensure that the submission provides sufficient information to identify the version of the standard and the specific provisions with which the manufacturer intends to conform. Reviewers should clearly indicate in their review memorandum that a statement about conformity with an FDA-recognized standard was provided and relied upon, and should specify the 510(k) requirements that the standard addressed.

XI. Performance Testing – Bench

(b)(4) Trade Secret Process - Testing

[redacted]

- (b)(4) Trade Secret Process - Testing

[redacted]

- (b)(4) Trade Secret Process - Testing [redacted]
- (b)(4) Trade Secret Process - Testing [redacted]

(b)(4) Trade Secret Process - Testing [redacted]

- (b)(4) Trade Secret Process - Testing [redacted]

XII. Performance Testing – Animal

None provided.

XIII. Performance Testing – Clinical

None provided.

XIV. Substantial Equivalence Discussion

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

5. Explain how descriptive characteristics are not precise enough:
The manufacturer needs to provide the results of testing that demonstrates substantial equivalence with respect to the performance of the Interlace Hysteroscopic Morcellation System when compared to the predicate given the differences in rotational speed, suction pressure, etc.

1. Explain what performance data is needed:
(b)(4) Trade Secret Process - Product Specification
[redacted]

XV. Deficiencies

The manufacturer was sent an e-mail on March 5th requesting the following additional information:

1. (b)(4) Trade Secret Process - Product Specification
[redacted]

2 (b)(4) Trade Secret Process - Product Specification
[redacted]

(b)(4) Trade Secret Process - Product Specification

[redacted]

3. (b)(4) Trade Secret Process - Product Specification

[redacted]

XVI. Contact History

2/27/08	**FDA e-mail with deficiencies**
2/29/08	**Teleconference with Ron Adams to clarify some deficiencies**
3/3/08	**Manufacturers e-mail responses**
3/5/08	**FDA e-mail with remaining deficiencies/Notification of Hold Status**

XVII. Recommendation

Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: Class II
Product Code: HIH

Monica A Price
Reviewer

3/5/08
Date

Kathryn S. Dawe-Kopp for C. Pollard
Branch Chief

3/6/08
Date

54

Price, Veronica A.

From: Ron Adams [Ron@InterlaceMedical.com]
Sent: Monday, March 03, 2008 5:00 PM
To: Price, Veronica A.
Subject: RE: K073690 Interlace Medical Hysteroscopic Morcellation System
Attachments: fda510k_3654_safetyattachment.pdf; FDA-3654_IEC60601-1_gensafety.pdf; FDA-3654_IEC60601-2-18_endosafety.pdf; FDA_Form_3654_IEC_60601-1-2_2004.pdf; 01-001_A1 Morcellator Operating Manual.pdf; Morcellator 510kResponse080303.pdf

Please find our response attached along with a revised operating manual and the IEC standards outlined on form 3654. A second message with additional background attachments is forthcoming.

Regards,

Ron Adams
O 508-875-1343 ext. 102
M 508-944-5166

From: Price, Veronica A. [mailto:veronica.price@fda.hhs.gov]
Sent: Wednesday, February 27, 2008 4:25 PM
To: Ron Adams
Subject: K073690 Interlace Medical Hysteroscopic Morcellation System

Dear Mr. Adams,

I am in the midst of conducting an in-depth review of this file. There are several deficiencies that I have noted in the course of my review. I would like to work interactively with you to resolve them so that I can continue this review and avoid placing the file on hold. In order to accomplish this, I will need responses to the following noted deficiencies:

Device Description

1. (b)(4) Trade Secret Process - Product Specification [redacted]

2. (b)(4) Trade Secret Process - Product Specification [redacted]

3. (b)(4) Trade Secret Process - Product Specification [redacted]

4. (b)(4) Trade Secret Process - Product Specification [redacted]

(b)(4) Trade Secret Process - Product Specification [redacted]

5. (b)(4) Trade Secret Process - Product Specification [redacted]

6. (b)(4) Trade Secret Process - Product Specificat [redacted]

Performance Data

7. In Section IV Performance Testing, you have indicated that electrical safety and electromagnetic safety testing *will be* conducted on the Interlace Medical Hysteroscopic Morcellation System *prior to* marketing. Before a determination of substantial equivalence can be made, this testing will need to be conducted and certification that the referenced standards have been met provided. Please provide this information for review.

8. The Protocol Outline provided in Appendix B, refers to a live telesurgery presented at the 2007 AAGL Congress. If you have a videotape of this, we would appreciate it if you could send us a copy.

9. (b)(4) Trade Secret Process - Testing [redacted].

10. (b)(4) Trade Secret Process - Testing [redacted]

11. (b)(4) Trade Secret Process - Testing [redacted]

Labeling

12. (b)(4) Trade Secret Process - Testing [redacted]

13. (b)(4) Trade Secret Process - Testing [redacted]

14. (b)(4) Trade Secret Process - Testing [redacted]

I would appreciate your responses by c.o.b. by Monday, March 3rd. These responses may be submitted electronically. If you are unable to meet this deadline, then I will place the file on hold pending your formal response submitted via the Document Mail Center. If you need any further clarification on these issues, please feel free to contact me. I can be reached by e-mail on Thursday and Monday and by phone on Friday.

Sincerely,

Veronica Price
Biomedical Engineer
Obstetrics & Gynecology Devices Branch
FDA
(240) 276-4174
fax: (240) 276-4156
e-mail: veronica.price@fda.hhs.gov

Interlace™ MEDICAL

Memo

To: Veronica Price

From: Ron Adams

CC: Debbie Iampietro

Date: 3/3/2008

Re: Morcellator 510k Response

Captured below are our responses to the deficiencies as noted in your 2/27/2008 message.

Device Description

1. In Section II Device Description you have described a feature on the Control Unit which indicates whether vacuum is present. The picture provided shows a vacuum LED and a vacuum sensor.

Reply: Vacuum sensor is a flow switch that is attached to a vacuum tube. If the vacuum sensor senses flow, it changes the LED from Red to Green.

2. The sensor is used to detect whether there is suction. If suction is detected, then the morcellator function is enabled. Please provide additional details on how this sensor detects suction and how this information is used by the System to enable morcellation.

Reply: The vacuum sensor is a flow switch that detects flow. If flow is present, the switch is closed enabling the morcellator motors to run.

3. The operation of the cutter is not entirely clear. In the Device Description under Footswitch Operation, you state that the morcellator "speed, rotation direction, and oscillation rate are fixed and not able to be modified by the user." In the Principle of Operation, you state that the morcellator consists of a "rotating and reciprocating inner tube or cutter." Please provide additional details on the motion of the cutter both in terms of its rotation and translation when the footswitch is depressed. Does the cutter rotate in only one direction or does it oscillate? What is the rate of translation and does the cutter start in a closed position and then open?

Reply: Outer tube is stationary. Inner tube rotates is one direction. Inner tube rotates and translates simultaneously. The Interlace Medical inner tube translates at a rate of 2.8 cycles/sec while the predicate device translates at 2.6 cycles/sec. The submission should say the morcellator "speed, rotation direction, and *reciprocation* rate are fixed and not able to be modified by the user." The cutter starts in the closed position.

4. In the description of the Morcellator handpiece, you have stated that "the suction tubing is connected to a stainless steel barbed connector on the proximal end of the handpiece." However the picture provided in Figure 2 does not show a barbed connector. There is such a connector at the proximal end of the morcellator depicted in Figure 3. Please clarify this discrepancy.

Reply: We have an error in the submission. The sentence above Figure 2 should read "The ***Suction*** tubing is connected to a stainless steel barbed connector on the proximal end of the *single use surgical morcellator.*" and not handpiece as previously stated.

5. The Interlace Medical Disposable Hysteroscopic Morcellator Instructions for Use describe a retaining clip which "locks" the morcellator in place. Please provide the design/performance specifications for this component and the results of testing that demonstrates that these specifications are met.

Reply: Performance Specification: Morcellator must not detach from handpiece under loading conditions anticipated in clinical procedures. The two most likely loading conditions are the insertion and removal of the morcellator from the hysteroscope working channel. A test was conducted on predicate devices and the pull out force was > 20 lbs. We have conducted the same test on the Interlace Medical devices and the pull out force also exceeded 20 lbs.

6. Section III. Substantial Equivalence fails to include a comparison of the rotational speed. According to information provided elsewhere in the file, the rotational speed of the Interlace Morcellator is 6000 rpm and the rotational speed of the Smith & Nephew IUR Reciprocating Morcellator has a recommended speed of 1100 rpm. Please address this significant difference in rotational speed by assessing the risks associated with this increased speed and demonstrating that the risks have been adequately mitigated.

Reply: The morcellator rotation speed has been selected to optimize cutting performance. The tube inside a tube construction of the Interlace Medical morcellator is utilized in arthroscopy cutters commonly spun at speeds of 5,000 to 12,000 rpm (see attached pdf files for Stryker, Smith & Nephew, and Linvatec blades and 510k's K973195, K062849, and K990524 for corresponding control units).

Performance Data

7. In Section IV Performance Testing, you have indicated that electrical safety and electromagnetic safety testing *will be* conducted on the Interlace Medical Hysteroscopic Morcellation System *prior to* marketing. Before a determination of substantial equivalence can be made, this testing will need to be conducted and certification that the referenced standards have been met provided. Please provide this information for review.

Reply: Our electrical testing consultants are completing detailed test plans outlining each of the requirements of the IEC standards and the tests that will be conducted. While these detailed test plans are being developed, we have completed the Standards Data Report form (FDA 3654) for each of the IEC standards and the completed forms are attached. We request that the FDA accept certification to compliance with a recognized consensus standard as sufficient evidence to demonstrate the safety of the device. Please note that our Safety and EMC consultants are both members of the respective IEC subcommittees and they have advised us that the IEC 60601-1-1:2000 standard cited in "Section IV: Performance Testing" of the Submission is incorrect. Our system does not connect to peripheral devices such as CRT or LCD monitors and thus does not fall within the scope of the medical systems standard.

8. The Protocol Outline provided in Appendix B, refers to a live telesurgery presented at the 2007 AAGL Congress. If you have a videotape of this, we would appreciate it if you could send us a copy.

Reply: Unfortunately, the AAGL has not made the Live Telesurgery videos available for purchase yet but we are investing options with the Society to get a copy.

9. In the Equivalency Testing Summary provided in Attachment 4, there were six data points for the subject device and six for the predicate device. It is not clear whether one device was used on the 6 locations consecutively and then removed and replaced with the predicate device or if they were alternated. In addition, it is not clear if 6 separate fibroids were treated or 6 locations on the same fibroid. In addition, the size and location of the fibroid(s) was not specified. Please provide these additional details on the testing conducted.

Reply: The testing was conducted on a single, large fibroid in a water filled plastic container on a bench top (see attached photo). A large fibroid was chosen such that sample variation could be eliminated as a variable. The testing was conducted on an alternating basis between the two systems as a series of paired tests. The paired tests were conducted at six different locations on the fibroid to eliminate bias from the testing. One new cutter was used for all six measurements for each system.

10. The Detailed Study Protocol is not sufficiently detailed with respect to the test set-up. Please provide additional information on whether the device was inserted transcervically through an operative hysteroscope and whether fluid inflow/outflow was monitored with a fluid management system.

Reply: Testing was conducted on a laboratory bench top where the extirpated fibroid was held in a container filled with water (see attached photo). A hysteroscope was not utilized for visualization. A fluid management system pump was used only to periodically fill the plastic container to maintain the water level above the cutting location.

11. The results provided in Appendix A also need further clarification. Please comment on the note for the subject device which indicated that the "motor stopped at 2:00." In addition, please explain how the fluid volume was determined.

Reply: Surgeon did not feel that the morcellator was cutting effectively so the test was stopped. We noted the 2:00 minute stopping point so that we could calculate the resection rate. The morcellator was examined and found to be normal. The testing was resumed. The fluid volumes were measured using a calibrated canister (Bemis 3000 cc High Flow canister).

Labeling

12. In the Device Description you have indicated that the morcellator handpiece is covered with a protective sterile drape. This is presumably and "off the shelf" item. This information should be included in the Interlace Medical Hysteroscopic Morcellation System Operating Manual.

Reply: We will add a list of accessories to the Operating Manual and note the information on the sterile sheath we are recommending – Cone Instruments Ultrasound Probe Cover Kit, # 934430 or equivalent. See page 11 of Manual.

13. The Setup instructions included in the Operating Manual instructs the user to depress the footswitch pedal to confirm handpiece operation (step 6) prior to connecting the suction to the morcellator. As indicated in deficiency #1, it was our understanding that suction needed to be detected in order for the morcellator to be enabled. Please clarify how the device can be operated if the suction is not hooked up.

Reply: We made a mistake and lines 6 and 7 need to be switched so that the suction is connected before the foot pedal activation is done. See page 6 of Operating Manual for corrected instructions.

14. Figure 6. Morcellator Configuration Diagram in the Operating Manual shows a vacuum source. The vacuum source and tubing are off the shelf components which are not a part of this System per se. Please revise this manual to reflect that these are off the shelf components and provide some general specifications, e.g, P>600 mmHg.

Reply: Vacuum tubing was added to the list of accessories on page 11 and the vacuum pressure warning statement on page 2 was edited to include the P>600 mmHg specification.

Equivalency Testing Protocol – Extirpated Fibroid in water in container on bench top

Interlace Medical

Hysteroscopic Morcellation System

62

Preface / Contents / Glossary of Symbols

Preface

This manual provides the information you need to operate and maintain the Interlace Medical Hysteroscopic Morcellation System. It is essential that you read and understand all the information in this manual before using or maintaining the system.

Contents

Introduction, Indications for Use, and Contraindications
Introduction **pg. 2**
Indications for Use **pg. 2**
Contraindications **pg. 2**
Warnings and Precautions
Warnings **pg. 2**
Precautions **pg.3**
Electromagnetic Safety **pg. 3**
System Components
Morcellator Control Unit - Front Panel **pg. 4**
- Timer Display Window **pg. 4**
- Vacuum Light Indicator **pg. 4**
- Morcellator Footswitch and Handpiece Connectors **pg. 4**

Morcellator Control Unit - Rear Panel **pg. 5**
- Power Switch **pg. 5**

Morcellator Handpiece **pg. 5**
Morcellator **pg. 5**
Morcellator Footswitch **pg. 5**
Setup pg. 6
Operation pg. 8
Installing a Morcellator in the Morcellator Handpiece **pg. 8**
Footswitch Operation **pg. 8**
Cleaning
Morcellator Handpiece **pg. 8**
Morcellator Control Unit **pg. 8**
Footswitch **pg. 8**
Maintenance and Service
Electrical Interference **pg. 9**
Environmental Protection **pg. 9**
Preventive Maintenance **pg. 9**
Service Philosophy **pg. 9**
Handpiece Cables **pgs. 10**
Control Unit Fuses **pg. 10**

Troubleshooting pg. 10
Technical Specifications
Morcellator Control Unit **pg. 11**
Morcellator handpiece **pg. 11**
Morcellator Footswitch **pg. 11**
Warranty
New Product Warranty **# 12**
Service Warranty **# 12**
Figures
1) Morcellator Control Unit- Front Panel **# 4**
2) Morcellator Control Unit - Rear Panel **# 5**
3) Morcellator Handpiece **# 5**
4) Morcellator **# 5**
5) Morcellator Footswitch **# 5**
6) System Configuration **# 7**

I ON
Main electrical power on.

O OFF
Main electrical power off.

FOOTSWITCH
Foot pedal Control

CAUTION
See Instructions for use.

EQUIPMENT CLASSIFICATION
Type BF Equipment

REF

CATALOG NUMBER
Part number or reorder number

IPX8

Watertight Equipment
Per IEC 529

63

Introductions, Indications for Use, Contraindications

Introduction

The Interlace Medical Hysteroscopic Morcellation System is designed to meet the requirements of intrauterine morcellation.

A disposable straight surgical morcellator is inserted into a morcellator handpiece for tissue removal requirements. A footswitch allows you to control morcellator action by turning it off and on.

The Interlace Medical Hysteroscopic Morcellation System features many performance and ease-of-use advantages, including:

- A suction monitoring sensor that prohibits morcellation when no vacuum is detected.
- A timer display that shows morcellation duration.

Indications for Use

The Interlace Medical Hysteroscopic Morcellation System is intended for use in gynecological procedures by trained professional gynecologists to resect and remove endometrial tissue for the following indications

- Submucous myomas
- Endometrial polyps

Contraindications

The Interlace Medical Hysteroscopic Morcellation System should not be used with pregnant patients or patients exhibiting pelvic infection, cervical malignancies, or previously diagnosed endometrial cancer.

Warnings and Precautions

Please read this manual before using the Interlace Medical Hysteroscopic Morcellation System. The brief operating instructions in this guide will make the system easier to use, while the recommended maintenance procedures will ensure optimal performance over years of reliable use. Of course, as with any surgical instrument, there are important health and safety considerations. These are listed below and highlighted within the text.

WARNINGS

- Before using the morcellation system for the first time, you should review all available product information. You should be experienced in hysterscopic surgey with powered instruments. Healthy uterine tissue can be injured by improper use of the morcellator. Use every available means to avoid such injury.
- Read these instructions completely prior to use.
- If visualization is lost during any point in the procedure stop cutting immediately.
- Periodic irrigation of the morcellator tip is recommended to provide adequate cooling and to prevent accumulation of excised materials in the surgical site.
- Ensure that vacuum pressure > 600 mmHg is available before commencing surgery.
- **DANGER**: Risk of explosion if used in the presence of flammable anesthetics.
- If this unit is configured as part of a system, the entire system should be tested for compliance with IEC 60601-1-1.
- If the leakage current of the configured system exceeds the limits of IEC 60601-1-1, install an appropriately rated UL 2601-1/IEC 60601-1 approved isolation transformer and retest the system.
- The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:
    - Use of the accessory in the patient vicinity.

Precautions

Rx only

U.S. Federal law restricts this device to sale by or on the order of a physician.

- Prior to use, examine the device(s) for possible damage to assure proper functioning. If damaged, do not use.
- Only the Interlace Medical Disposable Morcellator can be used with the Interlace Medical Hysteroscopic Morcellation system. The morcellator is intended for single use only. Do not resterilize. Do not lubricate morcellator. Discard morcellator blade assembly after use.
- Use of reprocessed, single-use morcellator may permanently damage, impede performance, or cause failure of your Interlace Medical Hysteroscopic Morcellator. Use of such products may render any warranties null and void.
- Do not allow the rotating portion of any morcellator to touch any metallic object such as a hysteroscope or sheath. Damage to both instruments is likely. Damage to the morcellator can range from a slight distortion or dulling of the cutting edge to actual fracture of the tip in vivo. If such contact does occur, inspect the tip. If you find cracks, fractures or dulling, or if you have any other reason to suspect a morcellator is damaged, replace it immediately.
- Do not operate the handpiece in the open air for an extended period, as the lack of irrigation may cause the handpiece or a morcellator inserted into the handpiece to overheat and seize.
- Excessive leverage on the morcellator does not improve cutting performance and, in extreme cases, may result in wear and degradation of the inner assembly.
- Do not sterilize or immerse the Morcellator Control Unit in disinfectant.
- Do not cool the morcellator handpiece by immersing it in cold water.
- Electrical safety testing should be performed by a biomedical engineer or other qualified person.
- This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.

Electromagnetic Safety

- The Interlace Medical Hysteroscopic Morcellation System needs special precautions regarding Electromagnet Safety and needs to be installed and put into service according to the Electromagnet Safety information provided in this manual and the Interlace Medical Hysteroscopic Morcellation System Service Manual [Ref. 01-003]
- This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:
    - Reorient or relocate this equipment, the other equipment, or both.
    - Increase the separation between the pieces of equipment.
    - Connect the pieces of equipment into different outlets of circuits.
    - Consult a biomedical engineer.
- The following equipment performance is considered safety related performance. That is, the failure or degradation of this performance will pose a safety risk to the patient or operator of this equipment.
    - grounding scheme
    - handpiece operation

- Note: If the Interlace Medical Hysteroscopic Morcellation System is put into service in accordance to the safety instruction in this manual, the product should remain safe and provide the performance listed above. If the product fails to provide this level of performance, the procedure should be aborted and the biomedical staff alerted to the observed problem. The problem needs to be corrected before continuing or starting a new procedure.

- Portable and mobile RF communications equipment, including Cellular Telephones and other wireless devices can affect medical electrical equipment. To insure safe operation of the Interlace Medical Hysteroscopic Morcellation System, do not operate communications equipment or Cellular Telephones at a distance closer than specified in Table XYZ of the Interlace Medical Hysteroscopic Morcellation System's Service Manual [Ref. 01-003].

- The Interlace Medical Hysteroscopic Morcellation System is not designed to work with or in the vicinity of Electrical Surgical Equipment. If Electrical Surgical Equipment must be used in the same area as the Interlace Medical Hysteroscopic Morcellation System, the Interlace Medical Hysteroscopic Morcellation System should be observed for proper operation before performing a procedure. This includes operating the Electrical Surgical Equipment in its active mode at a power level suitable for the procedure.

- For more information regarding the Electromagnetic Safety of this product, please see the Interlace Medical Hysteroscopic Morcellation System Service Manual [Ref. 01-003].

System Components

Morcellator Control Unit

[REF 10-300]

Control Unit - Front Panel

The control unit front panel includes Morcellation Timer Display, Footswitch and Handpiece Connectors (Figure 1)

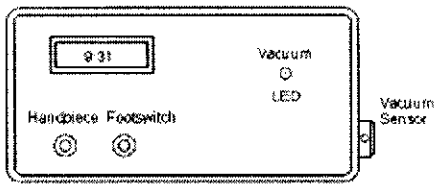


Figure 1 Hysteroscopic Morcellation Control Unit - Front panel

Timer Display Window

The control unit displays the elapsed morcellation time in MIN:SEC format.

Vacuum Light Indicator

The vacuum light indicator will glow GREEN when adequate vacuum is present and RED if it is not. The morcellator handpiece will not run if adequate vacuum is not present.

Footswitch and Handpiece Connectors

The Footswitch and Handpiece connectors are located on the front panel.

Control Unit - Rear Panel

There is one connector and a ground terminal on the rear panel (Figure 2).

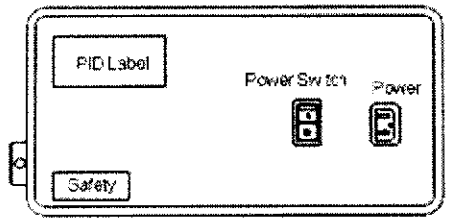


Figure 2 Hysteroscopic Morcellation System Control Unit - Rear panel

Power Switch

The rocker switch near the middle is the power ON / OFF switch for the entire system. The switch is illuminated when the system is ON.

Note: If system is turned off for any reason, wait at least 15 seconds before turning power back on.

The 3-pronged electrical connector allows any 100-120/200-240 VAC, 50/60 Hz, XXX VA source using the power cord supplied with the system. The control unit power supply automatically detects the local power standard and adapts the morcellator to that standard.

The Equipotential Compensator Terminal permits connection of the morcellator control unit to an external earthing system (not shown).

Morcellator Handpiece

[REF 10-100]

The Morcellator handpiece as shown in Figure 3) is a hand-held motor drive which is electrically connected to the control unit via a 10-foot (3-meter) cable and activated by a footswitch as seen in Figure 3.

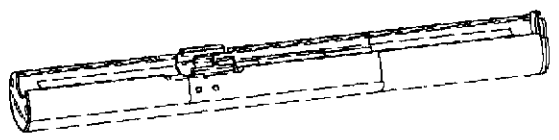


Figure 3 Morcellator Handpiece

Morcellator

[REF 10-200]

The morcellator is shown in Figure 4. It is a single use device designed to remove intrauterine tissue.

Figure 4 Morcellator

The suction tubing is connected to a stainless steel barbed connector on the proximal end of the morcellator. The suction pressure draws fluid and resected tissue through the morcellator window.

Footswitch

[REF 10-903]

The morcellation system footswitch controls morcellator operation (Figure 5). The footswitch plugs into the connector on the front of the control unit panel. It has a single pedal and is pneumatically operated.

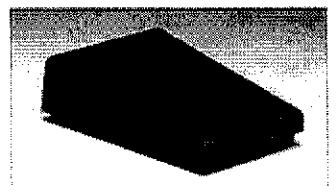


Figure 5. Footswitch

Setup

Setting up the Interlace Medical Hysteroscopic Morcellation System

WARNING-DANGER: Risk of explosion if used in the presence of flammable anesthetics

1. Review the System Configuration Diagram in Figure 6 for setup outline.

2. Place the morcellator control unit on top of a cart or other stable work surface. Plug the morcellator control unit power cord into the rear panel connector and a grounded AC power source.

3. Push the power switch on the ON (|) position.

4. Connect the morcellator handpiece cable to the front panel socket. The morcellator handpiece cable connector has a keyed feature that serves to align the handpiece cable to the morcellation control unit connector.

5. Connect the footswitch tube into the connector on the front of the control unit panel.

6. Connect the system to suction by attaching one section of suction tubing from the outflow connector on the proximal end of the morcellator to the canister and a second section from the vacuum sensor to the canister.

7. Press the footswitch pedal to confirm handpiece operation.

***CAUTION**: Do not operate the handpiece in the open air for an extended period, as the lack of irrigation may cause the handpiece or a morcellator inserted into the handpiece to overheat and seize*

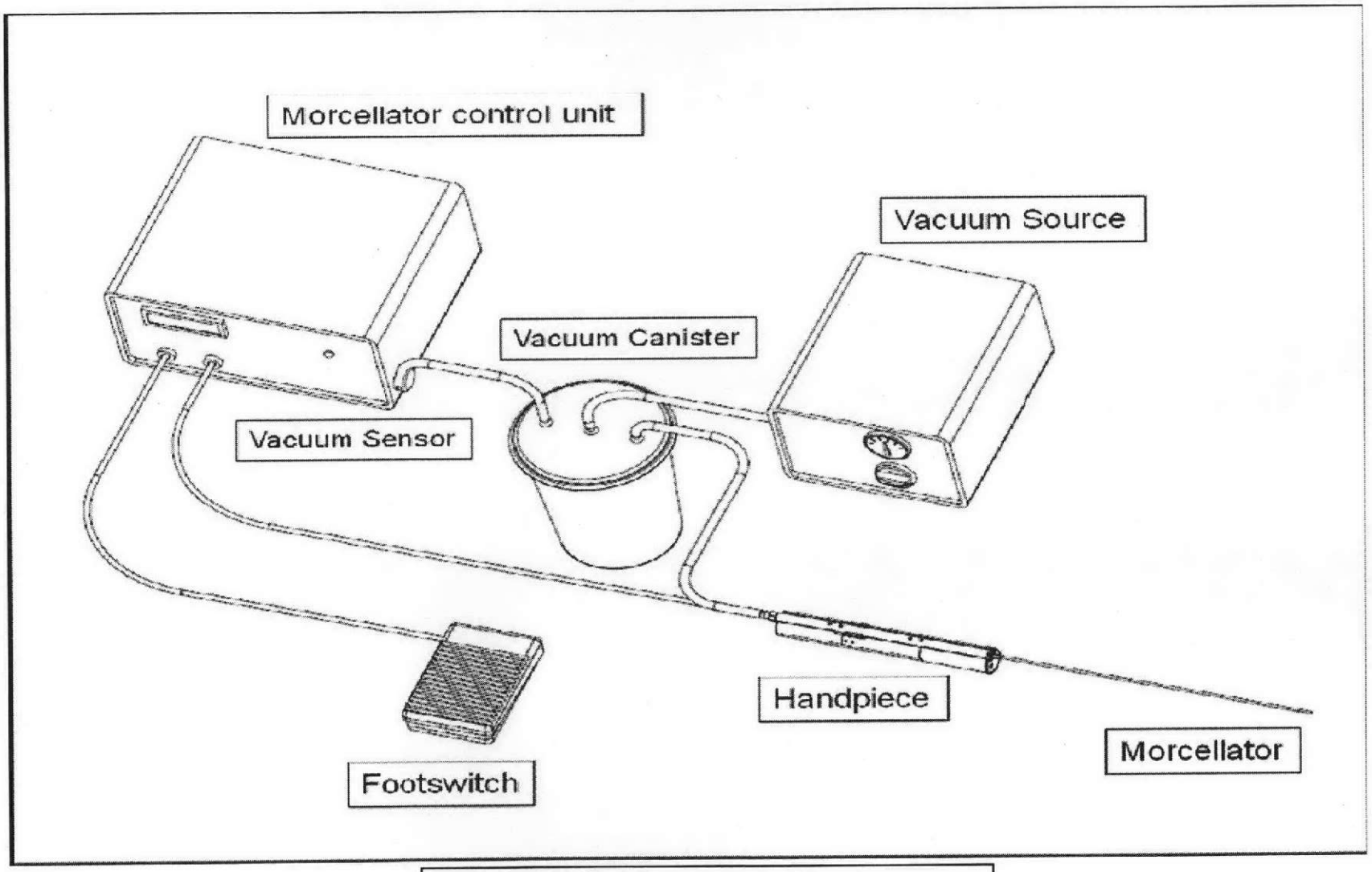


Figure 6. Morcellator Configuration Diagram

69

Operation

WARNING: Before using the morcellation system for the first time, you should review all available product information. You should be experience in hysteroscopic surgery with powered instruments. Healthly uterine tissue can be injured by improper use of the morcellator. Use every available means to avoid such injury.

1. Verify that the morcellator is sterile.

CAUTION: *Only Interlace Medical Disposable Morcellators can be used with the Interlace Medical Hysteroscopic Morcellation System. The morcellators are intended for single use only. Do not resterilize. Do not lubricate morcellator. Discard morcellator after use.*

Installing a Morcellator in the Morcellator Handpiece

1. Remove the morcellator [REF 10-200] from the sterile package. To insert a morcellator, follow the instructions in the Interlace Medical Disposable Hysteroscopic Morcellator Instructions for Use [REF 01-002].

2. Press the pedal on the footswitch and observe the morcellator action to verify that it is properly installed and operating.

WARNING: Periodic irrigation of the morecellator tip is recommended to provide adequate cooling and to precent accumulation of excised materials in the surgical site.

CAUTION: *Excessive leverage on the morcellator does not improve cutting performance and, inextreme cases, may result in wear and degradation of the inner assembly.*

NOTE: If system is turned off for any reason, wait at least 15 seconds before turning power back on.

Footswitch Operation

The footswitch [REF 10-903] activates morcellator operation. Since the morcellator operates in only one direction and speed, the footswitch merely turns the motor ON and OFF. Once the footswitch is depressed, the morclllator accelerates and rotates to the set speed and continues until the footswitch pedal is released.

Cutting takes place when the morcellator cutting edge rotates and translates across the morcellator's cutting window. The morcellator reciprocating action alternately opens and closes the window to the suction flow.

CLEANING

Morcellator Handpiece, Control Unit and Footswitch Cleaning

Follow this procedure after each operation to clean the control unit and the footswitch:

1. Disconnect the morcellator handpiece from the control unit.

2. Wipe the morcellator with a clean damp cloth and mild germicide or isopropyl alcohol.

3. Disconnect the control unit from the electrical source.

4. Wipe the control unit with a clean damp cloth and mild germicide or isopropyl alcohol.

CAUTION: *Do not sterilize or immerse the Morcellator Control Unit in disinfecant.*

5. Wipe the footswitch and the footswitch tube with a clean damp cloth.

The footswitch [REF 10-903] is watertight per IPX8.

Maintenance and Service

Maintenance

Electrical Interference

***Caution**: This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:*

- Reorient or relocate this equipment, the other equipment, or both.
- Increase the separation between the pieces of equipment between the pieces of equipment.
- Connect the pieces of equipment into different outlets or circuits.
- Consult a biomedical engineer.

Environmental Protection

***Caution**: This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.*

Preventative Maintenance

Recommended Annual Performance Checks

Interlace Medical recommends that Dielectric Strength, Earth Leakage Current, and Protective Earth Testing be performed annual to assure continued compliance with applicable safety requirements. These tests should be conducted in accordance with specifications UL 2601-1/IEC 60601-1.

***Caution**: Electrical safety testing should be performed by a biomedical engineer or other qualified person.*

Service

The following are replacement parts for the Interlace Medical Hysteroscopic Morcellation System:

REF	Description
10-900	Control Unit Power Cord
10-901	Handpiece Cable
10-902	Rear Panel Fuse: Replace With x.x amp/250V Quick Acting

Service Philosophy

There are no user serviceable components inside the Hysteroscopic Morcellation System Control Unit and Handpiece. Repairs and adjustments are to be performed only by Interlace Medical authorized service centers.

If service becomes necessary, call your authorized Interlace Medical Customer Service representative prior to returning the device and request a Return Authorization (RA) number. Your representative can also explain the available Service Replacement and Repair Programs.

Service items should be carefully repackaged and returned post-paid to Interlace Medical. Your Interlace Medical customer service representative can provide additional instructions.

Note: Product returned that is found to have been serviced by an unauthorized third party repair facility and/or cleaned with a unapproved biocide other than one approved by Interlace Medical will incur additional costs, regardless of warranty status.

It is not necessary to include accessory items (i.e., power cords, etc.) when returning a device for service.

Morcellator Handpiece Cables

Corrective maintenance involves field replacement of damaged handpiece cables. All other repairs should be performed at the factory or by Interlace Medical authorized service technicians.

1. The morcellator handpiece cable replacement is supplied in a kit with a set of installation instructions. Contact Interlace Medical Customer Service for assistance in obtaining a replacement.

Control Unit Fuses

The control unit is protected by dual x.x amp/250 V fuses mounted on the rear panel below the three-pronged electrical connector, and by a single x.x amp/250V fuse on the power supply board.

If the control unit fails to power up when properly connected to a 100-120/200-240 VAC, 50/60Hz, XXX VA, AC power source, check the fuses in the rear panel.

To change the rear panel fuses:

1. Disconnect the unit from the power source.
2. Locate the fuse tray just above the power cord socket and just below the fuse label (refer to Figure 2 rear panel view).
3. Use a slotted screwdriver to press the tabs on either side of the fuse holder in, toward the center of the tray.
4. Slide the fuse tray out.
5. Replace the fuses with x.x amp/250V Quick Acting fuses [REF 10-902]
6. Insert the tray into the holder until the tabs click into place.
7. Reapply power to the unit.

Note: Blown fuses usually indicate a short circuit or a failed component. Make sure components are properly interconnected. If the problem persists, contact Interlace Medical Customer Service for troubleshooting assistance.

***CAUTION**: Electrical safety testing should be performed by a biomedical engineer or other qualified person.*

Troubleshooting

The Interlace Medical Hysteroscopic Morcellation System is very simple to operate. The unit is switched ON using the rear panel power switch. If the unit does not operate, check the following:

1. Unit is plugged into wall outlet.
2. Wall outlet has power.
3. Power cord is attached to back of control unit.
4. Foot pedal has been connected to front panel.
5. Vacuum pressure is available.
6. Vacuum tubing is connected.

Note: If the system is turned off for any reason, wait at least 15 seconds before turning the power back on.

Technical Specifications

Morcellator Control Unit

[REF 10-300]

Dimensions
X wide by Y deep x Z High (XM x YM x ZM)

Weight
TBD Lbs (kg)

Power
100 – 120 / 200 -240 VAC, 50/60 Hz, 350 VA

Equipment Classification
Protection against electrical shock class 1 with BF type applied part. Protection against harmful ingress of water.

Degree of safety of application in the presence of flammable anesthetics with mixture of air, oxygen, or nitrous oxide. (Not suitable)

Mode of Operation
Continuous operation with short-time loading.

Front Panel

Time display window
6-character by one-line numeric display which indicates elapsed time Min:Sec

Connectors
Handpiece cable connetor for handpiece control.

Footswitch cable connector for foot control.

Rear Panel

Power ON/OFF
Illuminated rocker switch

Cooling
None required

AC Power
Detachable power cord with a three-pin hospital-grade connector. Power input circuit automatically detects AC power standard.

Ground Terminal
Equipotential Compensator Terminal

Fuses
Two x.x amp/250 V Quick Acting fuses [REF 10-902]

Morcellator Handpiece [REF 10-100]

Length
TBD

Weight
TBD

Equipped with 10-foot (3-meter) replaceable morcellator handpiece cable.

Morcellator [REF 10-200]

Length
TBD

Weight
TBD

Morcellator Footswitch

[REF 10-903]

Dimensions
4" x 6" x 2"

Weight
3.7 lbs

Equipped with 12 foot (3.6 meter) cord. The Footswitch [REF 10-903) is watertight per IPX8.

Morcellator Accessories

Sterile sheath – Cone Instruments Ultrasound Probe Cover Kit# 934430 or equivalent

Suction tubing – Ace Surgical suction tube #0034240 or equivalent

NEW PRODUCT WARRANTY

Interlace Medical products are guaranteed to be free from defects in material and workmanship for one year beginning from date of invoice.

This limited warranty is restricted to repair or replacement by Interlace Medical, at its option, of any product found to be defective during the warranty period. Damage inflicted to a product by the user that causes it to be unsuitable for refurbishment may result in additional charges, regardless of warranty status. All warranties apply to the original buyer only. In no event shall Interlace Medical be liable for any anticipated profits, consequential damages or loss of time incurred by the buyer with the purchase or use of any product.
NO OTHER WARRANTY, EXPRESSED OR IMPLIED, IS GIVEN.

SERVICE WARRANTY

Service Replacement Units Warranty

The Interlace Medical Hysteroscopic Morcellation System replacement unit is warranted to be free from defects in material and workmanship for 90 days from the date of original invoice unless otherwise provided by local law.

EC	REP

European Representative
Street Address
City, Postal Code
Country

Service Replacement Program

Interlace Medical offers a 24-hour Service Replacement Program for its products to minimize downtown in your operating room. Our goal is to ship you a service replacement unit within 24 hours** of your call (during normal business hours). For a Return Authorization (RA) number or for additional information on this program, call Customer Service 1-508-875-1343 in the U.S., or contact your authorized representative.

**24-hour shipment is not offered in all countries

Repair Service Program

For devices no longer under warranty, repairs can be made by Interlace Medical or by an authorized agent. Non-warranty repairs will be made at the list price of replacement parts, plus labor. If requested, we will provide an estimate of repair cost and time required for the repair before any work is done. Repair items should be carefully repackaged, market with the Return Authorization (RA) number, and returned postpaid to the appropriate Interlace Medical Service Center. Interlace Medical Customer Service or your local authorized representative can provide shipping information.

The Interlace Medical Hysteroscopic Morcellation System and components are covered by one or more of the following U. S. Patent Numbers: patents pending

H

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

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]
Item #4: Medical Electrical Equipment - Part 1: General Requirements for Safety, 60601-1 (1988); Amendment 1, 1991-11, Amendment 2, 1995

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 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 the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

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

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name 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 of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

PSC Graphics: (301) 443-1090 EF

15

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
TEM #4: MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR SAFETY, 60601-1 (1988); AMENDMENT 1, 1991-
, AMENDMENT 2, 1995

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Safety standard refers to Clauses. For all applicable clauses, see Attachment A	see Attachment A	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆
No deviations selected. Details are in Attachment A

DESCRIPTION
The Interlace Medical device will comply, before any shipments to customer, with all the applicable geneal safety requirements in IEC 60601-1:1988-1995. The compliance criteria will be that specified by the safety standard. See Attachment A for details.

JUSTIFICATION
At the time of this submission, Safety test data was not available but Interlace Medical intends to fully comply with the Safety requirements in IEC 60601-1 and all supplemental information requested by the FDA's extent of recognition.

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.

◆ 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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.

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

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]
Item #42: Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment 60601-2-18 (1996) Amendment 1 2000

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 42	
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 the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

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

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name 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 of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

PSC Graphics: (301) 443-1090 EF

78

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ITEM #42: MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ENDOSCOPIC EQUIPMENT 60601-2-18 (1996) AMENDMENT 1 2000

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Safety standard refers to Clauses. For all applicable clauses, see Attachment A	see Attachment A	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆
No deviations selected. Details are in Attachment A

DESCRIPTION
The Interlace Medical device will comply, before any shipments to customer, with all the applicable particular safety requirements in IEC 60601-2-18:1996-2000. The compliance criteria will be that specified by the safety standard. See Attachment A for details.

JUSTIFICATION
At the time of this submission, Safety test data was not available but Interlace Medical intends to fully comply with the Safety requirements in IEC 60601-2-18 and all supplemental information requested by the FDA's extent of recognition.

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

TYPE OF DEVIATION OR OPTION SELECTED◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
NA		☐ 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.

◆ 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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.

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

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]
Item 34: IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)).

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 013	
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?	☐	☐
'oes 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 the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

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

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name 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 of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

PSC Graphics: (301) 443-1090 EF

81

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ITEM 34: IEC 60601-1-2, MEDICAL ELECTRICAL EQUIPMENT - PART 1-2: GENERAL REQUIREMENTS FOR SAFETY - COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS (EDITION 2:2001 WITH AMENDMENT 1:2004; EDITION 2.1 (EDITION 2:2001 CONSOLIDATED WITH AMENDMENT 1:2004)).

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED◆
No deviation from this standard is proposed.

DESCRIPTION
The Interlace Medical device will comply, before any shipments to customer, with all the EMC requirement in IEC 60601-1-2:2004. The compliance criteria to be applied to this device will be as listed in Subclause 36.202.1 j) of this standard. The essential performance referred to in this subclause will be the performance specified by the manufacture for its intended use.

JUSTIFICATION
At the time of this submission, EMC test data was not available but Interlace Medical intends to fully comply with the EMC requirements in IEC 60601-1-2 and all supplemental information requested by the FDA's extent of recognition.

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.

◆ 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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.

Attachment A

To Summary Report Table, FDA Form 3654
For FDA Consensus Safety Standards: IEC 60601-1, and IEC 60601-2-18

Date: 3 March 2008

The System is currently under evaluation by (b)(4) Trade Secret Process - Product Specification [redacted] for compliance with applicable safety standards. Principal engineer of OBCM has over 25 years experience evaluating medical device safety. OBCM operates under an ISO/IEC 17025:2005 quality system. (b)(4) Trade [redacted] is certified by (b)(4) Trade Secret Process [redacted] as a Partner Test Laboratory (PTL).

Medical Device:

Interlace Medical, Tissue morcellator system

Applicable FDA consensus safety standards for the tissue morcellator system are:

IEC 60601-1:1988 + A1:1991 + A2:1995, Medical Electrical Equipment, Part 1: General Requirements for Safety
UL 60601-1:2003, US differences to IEC 60601-1
IEC 60601-2-18:1996 + A1:2000, Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment.

Electrical Ratings:

100-240 V~, 50-60 Hz, approx 200 VA.

Classifications:

Type of protection against electrical shock	Class I
Degree of protection against electrical shock	Type BF
Degree of protection against ingress of liquids	Control box: IPX0, ordinary Foot switch: IPX8, submersible Hand piece: IPX2, 15° drip
Disinfection, Sterilization	Control box: Disinfect with damp cloth Hand piece: Sterile, single use
Degree of safety in presence of flammable anesthetics	Not suitable
Mode of operation	Continuous

Environmental Conditions, Transportation and Storage:

Acceptable Temperature Range	-15°C to 40°C (5° F to 104° F)
Relative Humidity	10 to 93 %RH
Air Pressure	500 to 1060 kPa (15 to 31 inHg)

Environmental Conditions, Operation:

Acceptable Temperature Range	10°C to 40°C (50° F to 104° F)
Relative Humidity	30 to 75 %RH
Air Pressure	700 to 1060 kPa (21 to 31 inHg)

Insulation Diagram:

The following is an Insulation Diagram for the Morcellator System:

(b)(4) Trade Secret Process - Product Specification

[redacted]

Area	Insulation	Reference Voltage	Creepage, mm	Clearance, mm	Dielectric Strength, kVac
A	Double / Reinforced, A-a2	240 Vac	8	5	4
B	Basic, A-a1	240 Vac	4	2.5	1.5
C	Double / Reinforced, A-e	240 Vac	8	5	4
D	Double / Reinforced, B-a, B-e	12 Vdc	4	2.5	1.5
	Basic, B-d	240 Vac			
E	Double / Reinforced, B-a, B-e, IEC 60601-2-18, IEC 60664-1, PD1	24 Vdc	1.5	1.5	0.5
F	Double / Reinforced, B-a	240 Vac	8	5	4

Note: Insulation areas B, C, and D are predominately dependent on mains power supply construction. Power supply will be off-the-shelf type with NRTL medical certification for this insulation scheme.

The following is a summary of the Safety evaluation, including verification testing, which will be performed on the tissue morcellator system.

- Table I is the safety checklist for the general standard, IEC 60601-1.
- Table II is the safety checklist for the particular standard, IEC 60601-2-18.

Possible verdicts used in the Tables are:

- NA=Not applicable
- TBD=To be determined
- Pass=Found in compliance
- Fail=Found not in compliance

TABLE I

IEC 60601-1:1988 + A1:1991 + A2:1995, Medical Electrical Equipment, Part 1: General Requirements for Safety; and UL 60601-1:2003, US differences to IEC 60601-1.

Clause	Description	Remarks	Verdict
3.1	Acceptable risk in normal, foreseeable misuse, and single fault conditions	See TBD comments below	TBD
3.4	Alternative means to verify acceptable risk employed		NA
3.10DV	UL components	Power supply, mains components, and fire enclosure will have prior NRTL marks. Motor controller and motor will be evaluated as part of end-product.	Pass
5	Classifications	System is classified Class I, IPx0, not suitable for flammable anesthetics, continuous use. Disinfect with damp cloth. Footswitch is pneumatic; IPx8 not needed. Applied part hand piece is classified as BF, Ipx2. Single use, sterile.	Pass
6.1	Marking on outside of equipment	System will have manufacturer, model designation, electrical ratings, BF, symbol 14.	Pass
6.2	Marking on inside of equipment	No inside marking needed for system	NA
6.3	Marking of controls	AP and footswitch connectors marked.	Pass
6.4	Symbols	No special symbols	Pass
6.5	Colors of insulation		Pass
6.6	ID of medical gases		NA
6.7	Indicator lights and push-buttons		NA
6.8	Accompanying documents	Manual will have warnings, operation, cleaning, and technical specs. Service to be done by Interlace Med.	Pass
7	Power input	Must verify that input current under maximum normal loading is in accordance with nameplate rating.	TBD
10	Environmental conditions	Storage and operating to be established and put in accompanying documents based on accessory ratings.	TBD
14	Requirements related to classification		Pass
15	Limitation of voltage and/or energy	Must verify that inlet discharge after 1 s is under specified limits for across mains, and	TBD

Clause	Description	Remarks	Verdict
		mains to earth.	
16	Enclosure	Control box and hand piece enclosures to require tool to open. All connector/plugs are in place during use.	Pass
17	Separation	See prior insulation diagram.	TBD
18	Protective earthing, functional earthing, potential equalization	Must verify earth impedance from any earthed surface to be verified as < 100 mOhm to appliance inlet of isolation transformer	TBD
19	Leakage current	Must verify earth leakage, enclosure leakage, patient leakage, patient leakage with mains on BF part.	TBD
19.5DV	300 uA limit for earth leakage, earth open, and other US related limits.	Must verify earth and enclosure leakage to lower US limits.	TBD
20	Dielectric strength	See insulation diagram. Must verify dielectric strength.	TBD
21	Mechanical strength	Verify control box and hand piece enclosures comply with 21a push testing to be conducted. 21b impact test (0.5 J) to be represented by UL ball impact (5 J).	TBD
22	Moving parts	A footswitch will be needed to initiate motor(s). Should be type that control motion with continuous activation of footswitch, (deadman man type). See Clause 22.4. Based on risk assessment will determine if emergency off is required. Footswitch is pneumatic. Clause 56.10 is NA. Issues regarding liquid ingress and earthing of F-type circuit are NA.	TBD
23	Surfaces, corners, and edges	System to be checked for sharp edges	TBD
24	Stability	To verify that 10 degree tip of control box returns to stable rest position.	TBD
25	Expelled parts		NA
28	Suspended masses	No support systems.	NA
29	X-radiation	No CRT's	NA
36	EMC	Covered by separate checklist.	NA
37-41	AP and APG	not suitable	NA
42	Excessive Temperatures	Control box and hand piece to be loaded to maximum normal load, and operating temperatures of components/materials to be verified to limits.	TBD
43	Fire prevention		Pass
44.2	Overflow		NA
44.3	Spillage	200 ml test to be verified on control box.	TBD
44.4	Leakage	No fluid systems	NA

Clause	Description	Remarks	Verdict
44.5	Humidity	To verify leakage current and dielectric strength after 2 day humidity conditioning	Pass
44.6	Ingress of liquids	Hand piece to be verified to Ipx2, IEC 60529	TBD
44.7	Cleaning, sterilization, and disinfection	Control box to be verified for disinfection with damp cloth. Hand piece is single use, sterile.	TBD
45	Pressure vessels and parts subject to pressure		NA
48	Biocompatibility	Biocompatibility of hand piece and tip verified with other separate test reports.	NA
49	Interruption of power supply		Pass
51	Protection against hazardous output		Pass
52.1	Programmable electronic medical systems (PEMS) comply with IEC 60601-1-4	Morcellator system cuts away max 3 mm of endiometriumendometrial. This is within normal monthly loss during menstrual cycle. From an IEC 60601-1 basic safety point of view, don't need IEC 60601-1-4 compliance, since not mitigating unwanted motion. See Clause 22.	Pass
52.5.2	Failure of thermostats		NA
52.5.3	Short circuiting of either constituent of double insulation		NA
52.5.5	Impairment of cooling	Block any vent openings	TBD
52.5.6	Locking of moving parts	Block tool tip	TBD
52.5.7	Interruption and short-circuiting of motor capacitors		NA
52.5.8	Additional abnormal tests for motor operated equipment	Servo controlled motors	NA
55DV	UL fire enclosure, flame spread, ball impact, oven conditioning	To verify that plastic enclosure for control box complies with: portable fire enclosure requirement of min. V-2 flame rating, 50 cm ball impact, and 70 C oven conditioning. No metalized coating of plastic anticipated.	TBD
56.1	Safety critical components	See 3.10DV	TBD
56.2	Screws and nuts		NA
56.3	Connections – general		Pass
56.4	Connections of capacitors		NA
56.5	Protective devices		NA
56.6	Temperature and overload control devices		NA

Clause	Description	Remarks	Verdict
56.7	Batteries		NA
56.8	Indicators		NA
56.9	Pre-set controls		NA
56.10	Actuating parts of controls		NA
56.11	Cord-connected hand-held and foot-operated control devices	Hand piece is applied part.	TBD
57DV.1	Mains connection of permanently connected equipment compatible with NFPA 70	Not permanently connected	NA
57.1	Isolation from mains supply	DPST on/off switch.	Pass
57.2	Mains connectors, appliance inlets, and the like	Nondetachable cord with plug, or inlet. Final construction to be determined.	TBD
57.2DV	Hospital grade plugs and marking	HG plug and tag	TBD
57.3	Power supply cords	SV or SJ, min 0.75 mm^2 / 18 AWG to be verified	TBD
57.4	Connection of power supply cords	Nondetachable cord will need pull, twist and bending verification.	TBD
57.5	Mains terminal devices and writing of mains parts	Nondetachable cord will need suitable terminal block	TBD
57.6	Mains fuses and over-current releases		TBD
57.8	Wiring of the mains part		TBD
57.9	Mains supply transformer	To be part of NRTL medical certified power supply	TBD
57.10	Creepage distances and air clearances	See insulation diagram	TBD
58	Protective earthing, terminals and connections		TBD
59.1	Internal wiring		TBD
59.2	Insulation	To verify plastic enclosure 75 C ball pressure indent, and suitable terminal blocks based on certifications or 125 C ball pressure.	TBD
59.3	Excessive current and voltage protection		NA
59.4	Oil containers		NA
60DV	Separate power units	none	NA

TABLE II

IEC 60601-2-18:1996 + A1:2000, Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment.

Clause	Description	Remarks	Verdict
5	Classifications	Delete type B	Pass
6.8	Instructions for use	Verify applicable endoscopic advise is provided.	TBD
20	Dielectric strength	Minor wording clarifications	NA
21	Mechanical strength	Part 1 clause does not apply to hand piece, but intention remains to use Part 1 clause to verify suitability of hand piece.	TBD
22	Moving parts	Part 1 clause does not apply to hand piece, but intention remains to use Part 1 clause to verify suitability of hand piece.	TBD
25	Expelled parts	Part 1 clause does not apply to hand piece, but intention remains to use Part 1 clause to verify suitability of hand piece.	TBD
27	Pneumatic and hydraulic power	Part 1 clause does not apply to hand piece.	NA
42	Temperatures	No light part. No RF Vp rating	NA
44	Liquids, Ingress, Humidity, Cleaning, Sterility	Default sterility settings given.	NA
56.3	Connections	Part 1 clause does not apply to hand piece, but intention remains to use Part 1 clause to verify suitability of hand piece.	TBD
57.10	Creepage and Clearance	Hand piece to be verified for distances given in IEC 60664-1, pollution degree 1.	TBD

Price, Veronica A.

From: Ron Adams [Ron@InterlaceMedical.com]
Sent: Monday, March 03, 2008 5:02 PM
To: Price, Veronica A.
Subject: RE: K073690 Interlace Medical Hysteroscopic Morcellation System
Attachments: Linvatec Blade Chart.pdf; StrykerShaver.pdf; SN Chart.pdf

Attached here are PDF's of predicate arthroscopy cutters that operate at speeds > 6000 rpm that are referenced in the response letter.

Regards,

Ron Adams
O 508-875-1343 ext. 102
M 508-944-5166

From: Price, Veronica A. [mailto:veronica.price@fda.hhs.gov]
Sent: Wednesday, February 27, 2008 4:25 PM
To: Ron Adams
Subject: K073690 Interlace Medical Hysteroscopic Morcellation System

Dear Mr. Adams,

I am in the midst of conducting an in-depth review of this file. There are several deficiencies that I have noted in the course of my review. I would like to work interactively with you to resolve them so that I can continue this review and avoid placing the file on hold. In order to accomplish this, I will need responses to the following noted deficiencies:

Device Description

1. [redacted] (b)(4) Trade S t

2. [redacted] (b)(4) Trade Secret

3. [redacted] (b) (4) Trad e Secr et Proc ess - consists footswitch

4. [redacted] (b) (4) Tra de Sec

92

	3.5mm	4.2mm	4.8mr
Cat. No.:	C9248	9247A	C9245
Length:	13cm	13cm	13cm
Max Speed:	6,000rpm	6,000rpm	6,000rp

	3.5mm	4.2mm
Cat. No.:	C9290	C9291
Length:	13cm	13cm
Max Speed:	6,000rpm	6,000rpm

	3.5mm	4.2mm
Cat. No.:	C9283	C9284
Length:	13cm	13cm
Max Speed:	6,000rpm	6,000rpm

	3.5mm	4.2mm
Cat. No.:	C9760	9761A
Length:	13cm	13cm
Max Speed:	6,000rpm	6,000rpm

	4.2mm
Cat. No.:	C9274
Length:	13cm
Max Speed:	6,000rpm

	4.0mm
Cat. No.:	H9101 H9101RH*
Length:	13cm
Max Speed:	10,000rpm

	3.5mm	4.5mm
Cat. No.:	H9110	H9111
Length:	13cm	13cm
Max Speed:	10,000rpm	10,000rpm

	4.5mm
Cat. No.:	H9118 H9118RH*
Length:	13cm
Max Speed:	10,000rpm

	4.0mm
Cat. No.:	H9121 H9121RH*
Length:	13cm
Max Speed:	10,000rpm

	4.5mm
Cat. No.:	H9131
Length:	13cm
Max Speed:	10,000rpm

	4.5mm
Cat. No.:	H9133
Length:	13cm

Stryker Formula Shaver Handpieces

Formula Shaver Handpieces

Each of Stryker's three Formula Shaver handpieces combines power and precision to offer maximum performance and comfort for today's surgeon. The most recently introduced Formula 180 Shaver handpiece offers users up to 12,000 RPMs, shaver blade recognition and programmable buttons, all within an ergonomic design.

Features & Benefits

The Formula Shaver handpieces include a variety of innovative features to provide maximum performance in the operating room:

- Shaver Blade Recognition
- Keypad
- Release Button
- Suction Lever

Related Products

- Cutters and Burs
- CORE Shaver System
- Universal Wireless Footswitch System
- RF Ablation System
- Fluid Management
- Micro Cart

Stryker Corporation or its divisions or other corporate affiliated entities own, use or have applied for the following trademark(s) or service mark(s): **3-Chip**, **Formula**. All other trademarks are trademarks of their respective owners or holders.

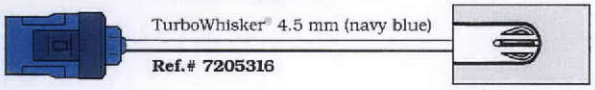
Smith+Nephew

IDENTIFICATION CHART

Color-Coded Disposable Arthroscopic Surgery Blades to fit the Dyonics® EP-1® Endoscopic Powered Instrument System*

Dyonics EP-1 disposable arthroscopy blades and burrs are offered in a wide array of options, including straight, curved and rotatable, in standard and long lengths. Diameter options include 3.5 mm, 4.0 mm, 4.5 mm and 5.5 mm blades and burrs, from the moderate TurboWhisker® edgeforms to the aggressive StoneCutter™ burrs. The Orbit® rotatable curved blades are designed to allow the cutting window to be customized to access hard-to-reach areas.

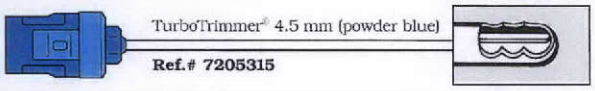
BLADES – Least Aggressive:



TurboWhisker® 4.5 mm (navy blue)

Ref.# 7205316

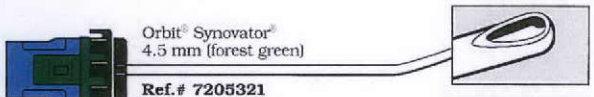
	Forward/Reverse
Speed Range:	**500-3000**
Initial Set Speed:	**2000**
Optimal Cutting Mode:	**Oscillate**



TurboTrimmer® 4.5 mm (powder blue)

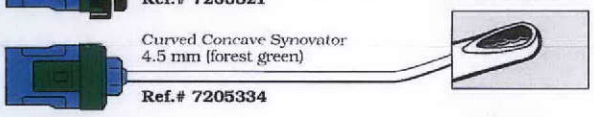
Ref.# 7205315

	Forward/Reverse	Oscillate
Speed Range:	**500-5000**	**500-3000**
Initial Set Speed:	**2000**	
Optimal Cutting Mode:	**Oscillate**	



Orbit® Synovator® 4.5 mm (forest green)

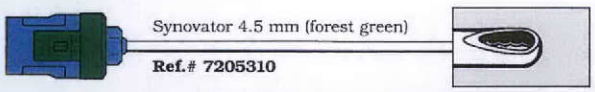
Ref.# 7205321



Curved Concave Synovator 4.5 mm (forest green)

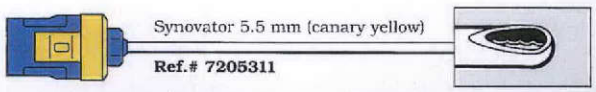
Ref.# 7205334

	Forward/Reverse	Oscillate
Speed Range:	**500-5000 (straight)** **500-3000 (curved)**	**500-3000**
Initial Set Speed:	**2000**	
Optimal Cutting Mode:	**Oscillate**	



Synovator 4.5 mm (forest green)

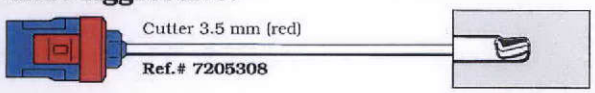
Ref.# 7205310



Synovator 5.5 mm (canary yellow)

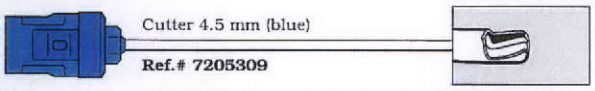
Ref.# 7205311

More Aggressive:



Cutter 3.5 mm (red)

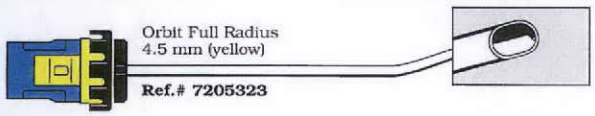
Ref.# 7205308



Cutter 4.5 mm (blue)

Ref.# 7205309

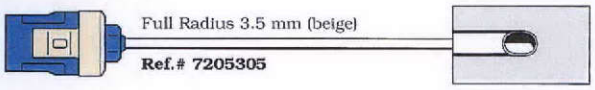
	Forward/Reverse	Oscillate
Speed Range:	**500-5000**	**500-3000**
Initial Set Speed:	**2000**	
Optimal Cutting Mode:	**Oscillate**	



Orbit Full Radius 4.5 mm (yellow)

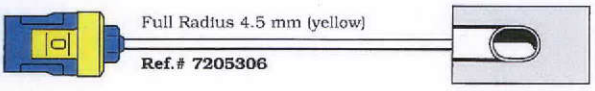
Ref.# 7205323

	Forward/Reverse	Oscillate
Speed Range:	**500-5000 (straight)** **500-3000 (curved)**	**500-3000**
Initial Set Speed:	**2000**	
Optimal Cutting Mode:	**Oscillate**	



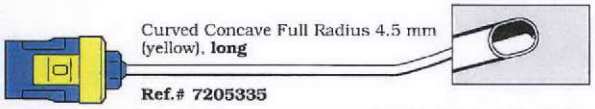
Full Radius 3.5 mm (beige)

Ref.# 7205305



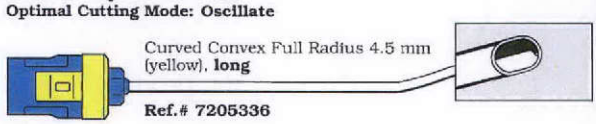
Full Radius 4.5 mm (yellow)

Ref.# 7205306



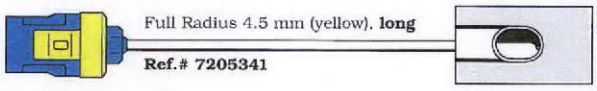
Curved Concave Full Radius 4.5 mm (yellow), **long**

Ref.# 7205335



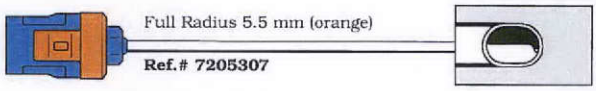
Curved Convex Full Radius 4.5 mm (yellow), **long**

Ref.# 7205336



Full Radius 4.5 mm (yellow), **long**

Ref.# 7205341



Full Radius 5.5 mm (orange)

Ref.# 7205307

Most Aggressive:

Incisor® Plus™ 4.5 mm (violet)
Ref.# 7205345

Incisor Plus 5.5 mm (teal)
Ref.# 7205459

	Forward/Reverse	Oscillate
Speed Range:	**500-5000 (straight)** **500-3000 (curved)**	**500-3000**
Initial Set Speed:	**2000**	
Optimal Cutting Mode:	**Oscillate**	

Orbit Incisor
4.5 mm (lime green)
Ref.# 7205320

Curved Concave Incisor
4.5 mm (lime green)
Ref.# 7205332

Incisor 3.5 mm (gray)
Ref.# 7205312

Incisor 4.5 mm (lime green)
Ref.# 7205313

Incisor 4.5 mm (lime green), **long**
Ref.# 7205343

Incisor 5.5 mm (mocha)
Ref.# 7205314

Orbit RazorCut® 4.5 mm (pink)
Ref.# 7205322

RazorCut 3.5 mm (purple)
Ref.# 7205317

RazorCut 4.5 mm (pink)
Ref.# 7205318

	Forward/Reverse	Oscillate
Speed Range:	**500-5000 (straight)** **500-3000 (curved)**	**500-3000**
Initial Set Speed:	**2000**	
Optimal Cutting Mode:	**Oscillate**	

RazorCut 5.5 mm (light pink)
Ref.# 7205319

BURRS – Least Aggressive:

	Forward/Reverse
Speed Range:	**500-8000**
Initial Set Speed:	**4000**
Optimal Cutting Mode:	**Forward**

Abrader 4.0 mm (aqua)
Ref.# 7205324

Abrader 5.5 mm (black)
Ref.# 7205325

Acromionizer 4.0 mm (mauve)
Ref.# 7205326

Acromionizer 5.5 mm (brown)
Ref.# 7205327

HeliCut™ 4.5 mm (slate)
Ref.# 7205727

Speed Range:	**500-5000**
Initial Set Speed:	**4000**
Optimal Cutting Mode:	**Forward**

Short Sheath 4.0 mm (maroon)
Ref.# 7205468

Short Sheath 5.5 mm (olive)
Ref.# 7205470

Most Aggressive:

	Forward/Reverse
Speed Range:	**500-8000**
4.0 mm Initial Set Speed:	**4000**
5.5 mm Initial Set Speed:	**4000**
Optimal Cutting Mode:	**Forward**

NotchBlaster® 4.0 mm (lilac)
Ref.# 7205328

NotchBlaster 5.5 mm (peach)
Ref.# 7205329

AcromioBlaster™ 4.0 mm (sage green)
Ref.# 7205668

AcromioBlaster 5.5 mm (brick red)
Ref.# 7205669

StoneCutter™ 4.0 mm (maroon)
Ref.# 7205330

StoneCutter 5.5 mm (olive)
Ref.# 7205331

Note: A separate mini blade/burr wall chart is available on request.

*See back of this chart for important Disposable Arthroscopic Surgery Blade Information.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

March 31, 2008

INTERLACE MEDICAL, INC.
139 NEWBURY STREET
FRAMINGHAM, MA 01701
ATTN: RON ADAMS

510(k) Number: K073690
Product: INTERLACE MEDICAL HYSTEROSCOPIC MORCELLATION

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K073690/S1

139 Newbury Street
Framingham, MA 01701
Tel: 508-875-1343
www.interlacemedical.com

Interlace MEDICAL

FDA CDRH DMC
MAR 28 2008
Received

March 27, 2008

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: Request for Information regarding 510 (k) Notification K073690

Dear Ms Price,

The enclosed information is in response to FDA's March 07, 2008 request for additional information regarding the Interlace Medical Hysteroscopic Morcellation System (K073690).

Should you need further information please feel free to contact me at any time.

Respectfully submitted,

Ron Adams

Ron Adams
Chief Technical Officer

Encl. Response Letter
Operating Manual
Handpiece Box Label

K22

Interlace MEDICAL

Memo

To: Veronica Price

From: Ron Adams

CC: Debbie Iampietro

Date: 3/27/2008

Re: Morcellator 510k Response

Captured below is the additional information as requested in your 3/5/2008 e-mail message.

1. (b)(4) Trade Secret Process - Product Specification [redacted]

(b)(4) Trade Secret Process - Product Specification [redacted]

Cutter Durability

(b)(4) Trade Secret Process - Product Specification [redacted]

(b)(4) Trade Secret Process - Product Specification

[redacted]

Heat Generation

(b)(4) Trade Secret Process - Product Specification

[redacted]

Table 1. Morcellator Comparison

Morcellator Comparison

(b)(4) Trade Secret Process - Product Specification

[redacted]

3/25/2008

21

(b)(4) Trade Secret Process - Product Specification

[redacted]

Figure 1. Morcellator Cutting Performance

Table 2. Morcellator Durability Comparison

(b)(4) Trade Secret Process - Product Specification

[redacted]

(b)(4) Trade Secret Process - Product Specification

[redacted]

Figure 2. Morcellator Heat Generation

Table 3. Morcellator Heat Generation Comparison

(b)(4) Trade Secret Process - Product Specification

[redacted]

2. In response to the 2/27 e-mail request from FDA to include information on the sterile drape that is to be used to cover the handpiece, you have revised your labeling to include recommended accessory equipment for use with the Interlace Morcellation System. This information is located at the end of the manual. This change is not sufficient to highlight the fact that the handpiece is provided non-sterile and must be covered with a sterile drape prior to use. Since this is a significant difference from the predicate handpiece which can be sterilized, additional details should be included in the labeling. Please revise your labeling to include a precaution that the handpiece cannot be sterilized and instead must be covered with a sterile drape. In addition, please emphasize the necessity of a sterile drape in either the section entitled, "Morcellator Handpiece" or "Setup."

Reply: Please see "Precautions" section of revised manual for statement indicating that handpiece is not sterilizable (pg. 3) and that the sterile draping technique as illustrated in the "Operation" section of the manual should be utilized (pg. 8, Figs. 7-9). The revised Handpiece Box Label follows the Operating Manual.

3. (b)(4) Trade Secret Process - Product Specification [redacted]

Interlace Medical

Hysteroscopic Morcellation System

Preface / Contents / Glossary of Symbols

Preface

This manual provides the information you need to operate and maintain the Interlace Medical Hysteroscopic Morcellation System. It is essential that you read and understand all the information in this manual before using or maintaining the system.

Contents

Introduction, Indications for Use, and Contraindications
Introduction **pg. 2**
Indications for Use **pg. 2**
Contraindications **pg. 2**
Warnings and Precautions
Warnings **pg. 2**
Precautions **pg.3**
Electromagnetic Safety **pg. 3**
System Components
Morcellator Control Unit - Front Panel **pg. 4**
- Timer Display Window **pg. 4**
- Vacuum Light Indicator **pg. 4**
- Morcellator Footswitch and Handpiece Connectors **pg. 4**

Morcellator Control Unit - Rear Panel **pg. 5**
- Power Switch **pg. 5**

Morcellator Handpiece **pg. 5**
Morcellator **pg. 5**
Morcellator Footswitch **pg. 5**
Setup pg. 6
Operation pg. 8
Installing a Morcellator in the Morcellator Handpiece **pg. 8**
Footswitch Operation **pg. 9**
Cleaning
Morcellator Handpiece **pg. 9**
Morcellator Control Unit **pg. 9**
Footswitch **pg. 9**
Maintenance and Service
Electrical Interference **pg. 10**
Environmental Protection **pg. 10**
Preventive Maintenance **pg. 10**
Service Philosophy **pg. 10**
Handpiece Cables **pgs. 11**
Control Unit Fuses **pg. 11**
Troubleshooting pg. 11
Technical Specifications
Morcellator Control Unit **pg. 12**
Morcellator Handpiece **pg. 12**
Morcellator Footswitch **pg. 12**
Morcellator Accessories **pg. 12**
Warranty
New Product Warranty **pg. 13**
Service Warranty **pg. 13**
Figures
1) Morcellator Control Unit- Front Panel **pg. 4**
2) Morcellator Control Unit - Rear Panel **pg. 5**
3) Morcellator Handpiece **pg. 5**
4) Morcellator **pg. 5**
5) Morcellator Footswitch **pg. 5**
6) System Configuration **pg. 7**
7) Install Sterile Drape **pg. 8**
8) Draping of Handpiece **pg. 8**
9) Draped Handpiece **pg. 8**

I ON
Main electrical power on.

O OFF
Main electrical power off.

FOOTSWITCH
Foot pedal Control

CAUTION
See Instructions for use.

EQUIPMENT CLASSIFICATION
Type BF Equipment

REF CATALOG NUMBER
Part number or reorder number

IPX8 Watertight Equipment
Per IEC 529

28

Introductions, Indications for Use, Contraindications

Introduction

The Interlace Medical Hysteroscopic Morcellation System is designed to meet the requirements of intrauterine morcellation.

A disposable straight surgical morcellator is inserted into a morcellator handpiece for tissue removal requirements. A footswitch allows you to control morcellator action by turning it off and on.

The Interlace Medical Hysteroscopic Morcellation System features many performance and ease-of-use advantages, including:

- A suction monitoring sensor that prohibits morcellation when no vacuum is detected.
- A timer display that shows morcellation duration.

Indications for Use

The Interlace Medical Hysteroscopic Morcellation System is intended for use in gynecological procedures by trained professional gynecologists to resect and remove endometrial tissue for the following indications

- Submucous myomas
- Endometrial polyps

Contraindications

The Interlace Medical Hysteroscopic Morcellation System should not be used with pregnant patients or patients exhibiting pelvic infection, cervical malignancies, or previously diagnosed endometrial cancer.

Warnings and Precautions

Please read this manual before using the Interlace Medical Hysteroscopic Morcellation System. The brief operating instructions in this guide will make the system easier to use, while the recommended maintenance procedures will ensure optimal performance over years of reliable use. Of course, as with any surgical instrument, there are important health and safety considerations. These are listed below and highlighted within the text.

WARNINGS

- Before using the morcellation system for the first time, you should review all available product information. You should be experienced in hysteroscopic surgery with powered instruments. Healthy uterine tissue can be injured by improper use of the morcellator. Use every available means to avoid such injury.
- Read these instructions completely prior to use.
- If visualization is lost during any point in the procedure stop cutting immediately.
- Periodic irrigation of the morcellator tip is recommended to provide adequate cooling and to prevent accumulation of excised materials in the surgical site.
- Ensure that vacuum pressure > 600 mmHg is available before commencing surgery.
- **DANGER**: Risk of explosion if used in the presence of flammable anesthetics.
- If this unit is configured as part of a system, the entire system should be tested for compliance with IEC 60601-1-1.
- If the leakage current of the configured system exceeds the limits of IEC 60601-1-1, install an appropriately rated UL 2601-1/IEC 60601-1 approved isolation transformer and retest the system.
- The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:
    - Use of the accessory in the patient vicinity.

Precautions

Rx only — U.S. Federal law restricts this device to sale by or on the order of a physician.

- Prior to use, examine the device(s) for possible damage to assure proper functioning. If damaged, do not use.
- Only the Interlace Medical Disposable Morcellator can be used with the Interlace Medical Hysteroscopic Morcellation system. The morcellator is intended for single use only. Do not resterilize. Do not lubricate morcellator. Discard morcellator blade assembly after use.
- Use of reprocessed, single-use morcellator may permanently damage, impede performance, or cause failure of your Interlace Medical Hysteroscopic Morcellator. Use of such products may render any warranties null and void.
- Do not allow the rotating portion of any morcellator to touch any metallic object such as a hysteroscope or sheath. Damage to both instruments is likely. Damage to the morcellator can range from a slight distortion or dulling of the cutting edge to actual fracture of the tip in vivo. If such contact does occur, inspect the tip. If you find cracks, fractures or dulling, or if you have any other reason to suspect a morcellator is damaged, replace it immediately.
- Do not operate the handpiece in the open air for an extended period, as the lack of irrigation may cause the handpiece or a morcellator inserted into the handpiece to overheat and seize.
- Excessive leverage on the morcellator does not improve cutting performance and, in extreme cases, may result in wear and degradation of the inner assembly.
- Do not sterilize or immerse the Morcellator Control Unit in disinfectant.
- Do not cool the morcellator handpiece by immersing it in cold water.
- Electrical safety testing should be performed by a biomedical engineer or other qualified person.
- This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.
- Do not sterilize the Morcellator Handpiece or immerse it in disinfecting solutions. It should be protected by a sterile drape during use – see "Operation" section.

Electromagnetic Safety

- The Interlace Medical Hysteroscopic Morcellation System needs special precautions regarding Electromagnet Safety and needs to be installed and put into service according to the Electromagnet Safety information provided in this manual and the Interlace Medical Hysteroscopic Morcellation System Service Manual [Ref. 01-003]
- This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:
    - Reorient or relocate this equipment, the other equipment, or both.
    - Increase the separation between the pieces of equipment.
    - Connect the pieces of equipment into different outlets of circuits.
    - Consult a biomedical engineer.
- The following equipment performance is considered safety related performance. That is, the failure or degradation of this performance will pose a safety risk to the patient or operator of this equipment.
    - grounding scheme
    - handpiece operation

- Note: If the Interlace Medical Hysteroscopic Morcellation System is put into service in accordance to the safety instruction in this manual, the product should remain safe and provide the performance listed above. If the product fails to provide this level of performance, the procedure should be aborted and the biomedical staff alerted to the observed problem. The problem needs to be corrected before continuing or starting a new procedure.

- Portable and mobile RF communications equipment, including Cellular Telephones and other wireless devices can affect medical electrical equipment. To insure safe operation of the Interlace Medical Hysteroscopic Morcellation System, do not operate communications equipment or Cellular Telephones at a distance closer than specified in Table XYZ of the Interlace Medical Hysteroscopic Morcellation System's Service Manual [Ref. 01-003].

- The Interlace Medical Hysteroscopic Morcellation System is not designed to work with or in the vicinity of Electrical Surgical Equipment. If Electrical Surgical Equipment must be used in the same area as the Interlace Medical Hysteroscopic Morcellation System, the Interlace Medical Hysteroscopic Morcellation System should be observed for proper operation before performing a procedure. This includes operating the Electrical Surgical Equipment in its active mode at a power level suitable for the procedure.

- For more information regarding the Electromagnetic Safety of this product, please see the Interlace Medical Hysteroscopic Morcellation System Service Manual [Ref. 01-003].

System Components

Morcellator Control Unit

[REF 10-300]

Control Unit - Front Panel

The control unit front panel includes Morcellation Timer Display, Footswitch and Handpiece Connectors (Figure 1)

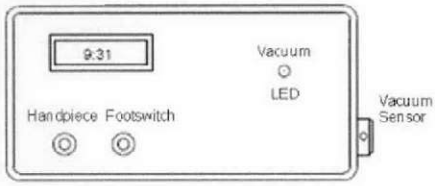


Figure 1 Hysteroscopic Morcellation Control Unit - Front panel

Timer Display Window

The control unit displays the elapsed morcellation time in MIN:SEC format.

Vacuum Light Indicator

The vacuum light indicator will glow GREEN when adequate vacuum is present and RED if it is not. The morcellator handpiece will not run if adequate vacuum is not present.

Footswitch and Handpiece Connectors

The Footswitch and Handpiece connectors are located on the front panel.

Control Unit - Rear Panel

There is one connector and a ground terminal on the rear panel (Figure 2).

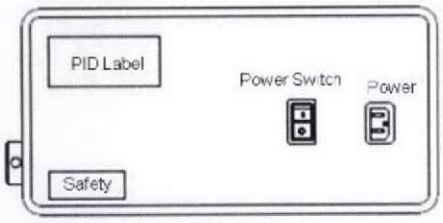


Figure 2 Hysteroscopic Morcellation System Control Unit - Rear panel

Power Switch

The rocker switch near the middle is the power ON / OFF switch for the entire system. The switch is illuminated when the system is ON.

Note: If system is turned off for any reason, wait at least 15 seconds before turning power back on.

The 3-pronged electrical connector allows any 100-120/200-240 VAC, 50/60 Hz, XXX VA source using the power cord supplied with the system. The control unit power supply

automatically detects the local power standard and adapts the morcellator to that standard. The Equipotential Compensator Terminal permits connection of the morcellator control unit to an external earthing system (not shown).

Morcellator Handpiece

[REF 10-100]

The Morcellator handpiece as shown in Figure 3) is a hand-held motor drive which is electrically connected to the control unit via a 10-foot (3-meter) cable and activated by a footswitch as seen in Figure 5.

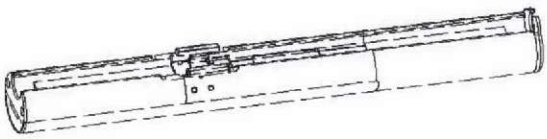


Figure 3 Morcellator Handpiece

Morcellator

[REF 10-200]

The morcellator is shown in Figure 4. It is a single use device designed to remove intrauterine tissue.

Figure 4 Morcellator

The suction tubing is connected to a stainless steel barbed connector on the proximal end of the morcellator. The suction pressure draws fluid and resected tissue through the morcellator window.

Footswitch

[REF 10-903]

The morcellation system footswitch controls morcellator operation (Figure 5). The footswitch plugs into the connector on the front of the control unit panel. It has a single pedal and is pneumatically operated.

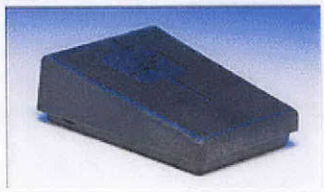


Figure 5 Footswitch

Setup

Setting up the Interlace Medical Hysteroscopic Morcellation System

WARNING-DANGER: Risk of explosion if used in the presence of flammable anesthetics

1. Review the System Configuration Diagram in Figure 6 for setup outline.
2. Place the morcellator control unit on top of a cart or other stable work surface. Plug the morcellator control unit power cord into the rear panel connector and a grounded AC power source.
3. Push the power switch on the ON (|) position.
4. Connect the morcellator handpiece cable to the front panel socket. The morcellator handpiece cable connector has a keyed feature that serves to align the handpiece cable to the morcellation control unit connector.
5. Connect the footswitch tube to the connector on the front of the control unit panel.
6. Connect the system to suction by attaching one section of suction tubing from the outflow connector on the proximal end of the morcellator to the canister and a second section from the vacuum sensor to the canister.
7. Press the footswitch pedal to confirm handpiece operation.

***CAUTION**: Do not operate the handpiece in the open air for an extended period, as the lack of irrigation may cause the handpiece or a morcellator inserted into the handpiece to overheat and seize*

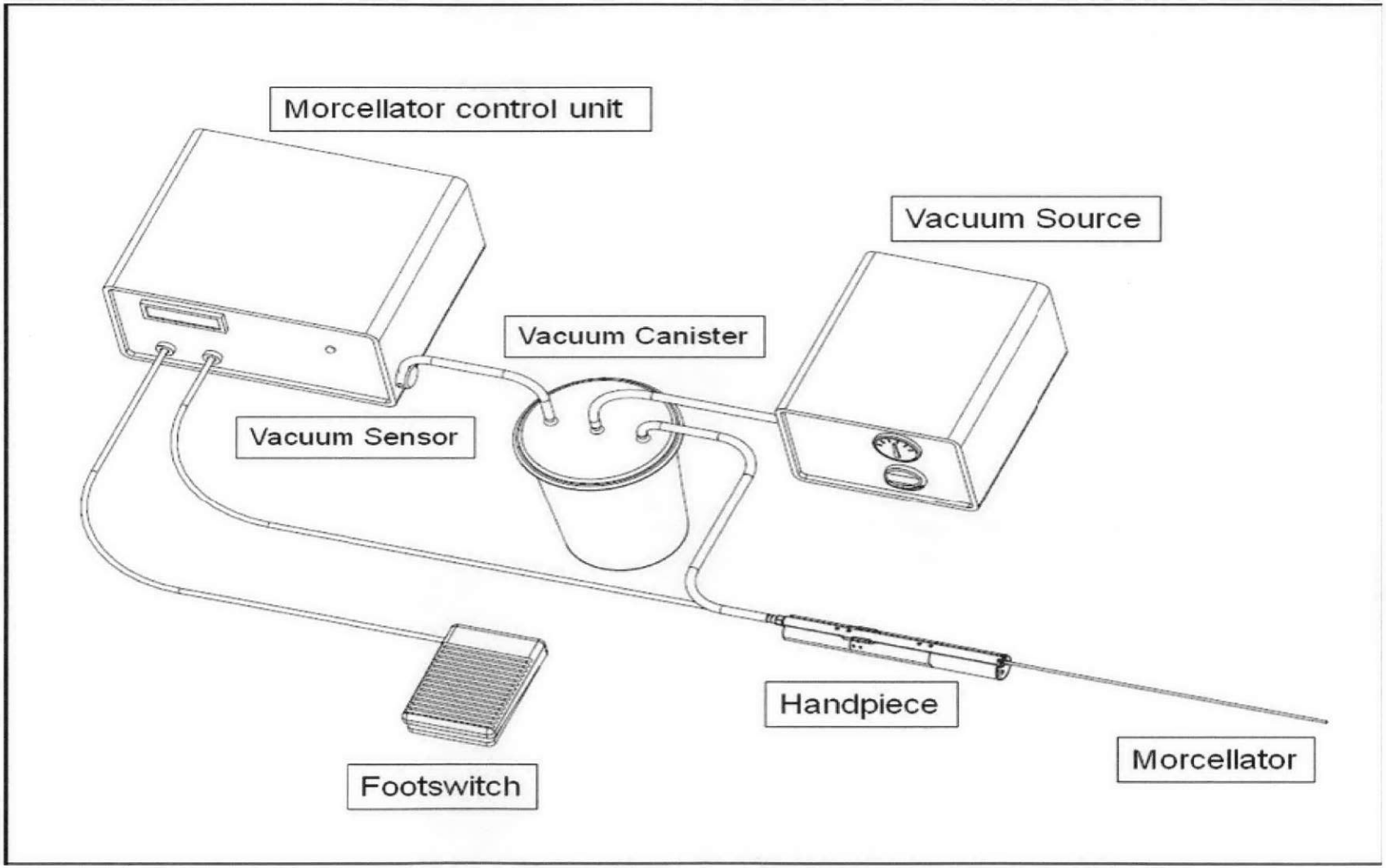


Figure 6 Morcellator Configuration Diagram

Operation

WARNING: Before using the morcellation system for the first time, you should review all available product information. You should be experience in hysteroscopic surgery with powered instruments. Healthly uterine tissue can be injured by improper use of the morcellator. Use every available means to avoid such injury.

1. Verify that the morcellator is sterile.

CAUTION: *Only Interlace Medical Disposable Morcellators can be used with the Interlace Medical Hysteroscopic Morcellation System. The morcellators are intended for single use only. Do not resterilize. Do not lubricate morcellator. Discard morcellator after use.*

Installing a Morcellator in the Morcellator Handpiece

1. Remove the morcellator [REF 10-200] from the sterile package.

2. While the non-sterile person holds the proximal end of the morcellator, the sterile person places the sterile drape over the distal tip of the morcellator and slides the drape down the morcellator shaft to the handpiece as shown in Figure 7.

Figure 7 Install Sterile Drape onto Morcellator

3. While the sterile person holds the morcellator and sterile drape, the non-sterile person pulls the drape down over the handpiece as shown in Figure 8.

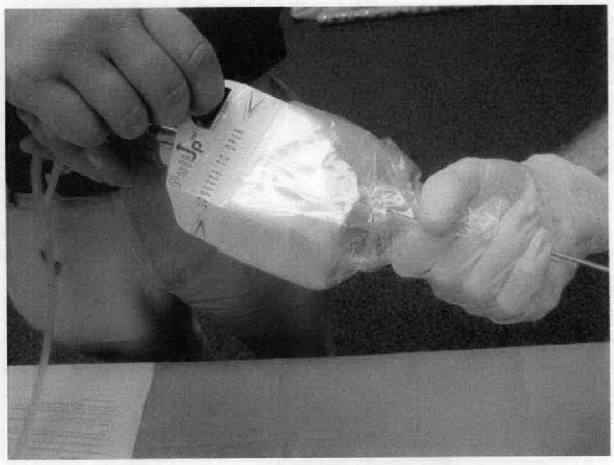


Figure 8 Draping of Handpiece

4. The non-sterile person will continue to pull the drape to cover the cabling connnected to the handpiece and tubing connected to the morcellator – Figure 9.

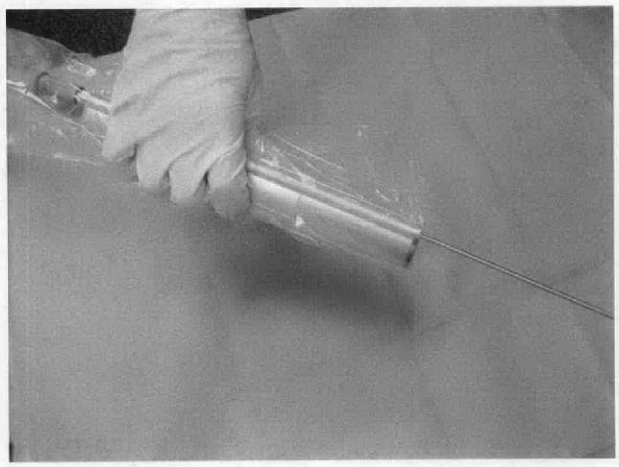


Figure 9 Draped Handpiece

5. Press the pedal on the footswitch and observe the morcellator action to verify that it is properly installed and operating.

WARNING: Periodic irrigation of the morecellator tip is recommended to provide adequate cooling and to prevent accumulation of excised materials in the surgical site.

CAUTION: *Excessive leverage on the morcellator does not improve cutting performance and, inextreme cases, may result in wear and degradation of the inner assembly.*

NOTE: If system is turned off for any reason, wait at least 15 seconds before turning power back on.

Footswitch Operation

The footswitch [REF 10-903] activates morcellator operation. Since the morcellator operates in only one direction and speed, the footswitch merely turns the motor ON and OFF. Once the footswitch is depressed, the morclllator accelerates and rotates to the set speed and continues until the footswitch pedal is released.

Cutting takes place when the morcellator cutting edge rotates and translates across the morcellator's cutting window. The morcellator reciprocating action alternately opens and closes the window to the suction flow.

CLEANING

Morcellator Handpiece, Control Unit and Footswitch Cleaning

Follow this procedure after each operation to clean the control unit and the footswitch:

1. Disconnect the morcellator handpiece from the control unit.

2. Wipe the morcellator handpiece with a clean damp cloth and mild germicide or isopropyl alcohol.

CAUTION: Do not sterilize the Morcellator Handpiece or immerse it in disinfecting solutions. It should be protected by a sterile drape during use – see "Operation" section.

3. Disconnect the control unit from the electrical source.

4. Wipe the control unit with a clean damp cloth and mild germicide or isopropyl alcohol.

CAUTION: *Do not sterilize or immerse the Morcellator Control Unit in disinfecant.*

5. Wipe the footswitch and the footswitch tube with a clean damp cloth.

The footswitch [REF 10-903] is watertight per IPX8.

Maintenance and Service

Maintenance

Electrical Interference

***Caution**: This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:*

- Reorient or relocate this equipment, the other equipment, or both.
- Increase the separation between the pieces of equipment between the pieces of equipment.
- Connect the pieces of equipment into different outlets or circuits.
- Consult a biomedical engineer.

Environmental Protection

***Caution**: This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.*

Preventative Maintenance

Recommended Annual Performance Checks

Interlace Medical recommends that Dielectric Strength, Earth Leakage Current, and Protective Earth Testing be performed annually to assure continued compliance with applicable safety requirements. These tests should be conducted in accordance with specifications UL 2601-1/IEC 60601-1.

***Caution**: Electrical safety testing should be performed by a biomedical engineer or other qualified person.*

Service

The following are replacement parts for the Interlace Medical Hysteroscopic Morcellation System:

REF	Description
10-900	Control Unit Power Cord
10-901	Handpiece Cable
10-902	Rear Panel Fuse: Replace With x.x amp/250V Quick Acting

Service Philosophy

There are no user serviceable components inside the Hysteroscopic Morcellation System Control Unit and Handpiece. Repairs and adjustments are to be performed only by Interlace Medical authorized service centers.

If service becomes necessary, call your authorized Interlace Medical Customer Service representative prior to returning the device and request a Return Authorization (RA) number. Your representative can also explain the available Service Replacement and Repair Programs.

Service items should be carefully repackaged and returned post-paid to Interlace Medical. Your Interlace Medical customer service representative can provide additional instructions.

Note: Product returned that is found to have been serviced by an unauthorized third party repair facility and/or cleaned with a unapproved biocide other than one approved by Interlace Medical will incur additional costs, regardless of warranty status.

It is not necessary to include accessory items (i.e., power cords, etc.) when returning a device for service.

Morcellator Handpiece Cables

Corrective maintenance involves field replacement of damaged handpiece cables. All other repairs should be performed at the factory or by Interlace Medical authorized service technicians.

1. The morcellator handpiece cable replacement is supplied in a kit with a set of installation instructions. Contact Interlace Medical Customer Service for assistance in obtaining a replacement.

Control Unit Fuses

The control unit is protected by dual x.x amp/250 V fuses mounted on the rear panel below the three-pronged electrical connector, and by a single x.x amp/250V fuse on the power supply board.

If the control unit fails to power up when properly connected to a 100-120/200-240 VAC, 50/60Hz, XXX VA, AC power source, check the fuses in the rear panel.

To change the rear panel fuses:

1. Disconnect the unit from the power source.
2. Locate the fuse tray just above the power cord socket and just below the fuse label (refer to Figure 2 rear panel view).
3. Use a slotted screwdriver to press the tabs on either side of the fuse holder in, toward the center of the tray.
4. Slide the fuse tray out.
5. Replace the fuses with x.x amp/250V Quick Acting fuses [REF 10-902]
6. Insert the tray into the holder until the tabs click into place.
7. Reapply power to the unit.

Note: Blown fuses usually indicate a short circuit or a failed component. Make sure components are properly interconnected. If the problem persists, contact Interlace Medical Customer Service for troubleshooting assistance.

***CAUTION**: Electrical safety testing should be performed by a biomedical engineer or other qualified person.*

Troubleshooting

The Interlace Medical Hysteroscopic Morcellation System is very simple to operate. The unit is switched ON using the rear panel power switch. If the unit does not operate, check the following:

1. Unit is plugged into wall outlet.
2. Wall outlet has power.
3. Power cord is attached to back of control unit.
4. Foot pedal has been connected to front panel.
5. Vacuum pressure is available.
6. Vacuum tubing is connected.

Note: If the system is turned off for any reason, wait at least 15 seconds before turning the power back on.

Technical Specifications

Morcellator Control Unit [REF 10-300]

Dimensions
X wide by Y deep x Z High (XM x YM x ZM)
Weight
TBD Lbs (kg)
Power
100 - 120 / 200 -240 VAC, 50/60 Hz, 350 VA
Equipment Classification
Protection against electrical shock class 1 with BF type applied part. Protection against harmful ingress of water.

Degree of safety of application in the presence of flammable anesthetics with mixture of air, oxygen, or nitrous oxide. (Not suitable)

Mode of Operation
Continuous operation with short-time loading.

Front Panel

Time display window
6-character by one-line numeric display which indicates elapsed time Min:Sec

Connectors
Handpiece cable connetor for handpiece control.
Footswitch cable connector for foot control.

Rear Panel

Power ON/OFF
Illuminated rocker switch
Cooling
None required
AC Power
Detachable power cord with a three-pin hospital-grade connector. Power input circuit automatically detects AC power standard.
Ground Terminal
Equipotential Compensator Terminal
Fuses
Two x.x amp/250 V Quick Acting fuses [REF 10-902]

.....

Morcellator Handpiece [REF 10-100]

Length
TBD
Weight
TBD
Equipped with 10-foot (3-meter) replaceable morcellator handpiece cable.

.....

Morcellator [REF 10-200]

Length
TBD
Weight
TBD

.....

Morcellator Footswitch [REF 10-903]

Dimensions
4" x 6" x 2"

Weight
3.7 lbs

Equipped with 12 foot (3.6 meter) cord. The Footswitch [REF 10-903) is watertight per IPX8.

.....

Morcellator Accessories

Sterile sheath
Cone Instruments Ultrasound Probe Cover Kit# 934430 or equivalent

Suction tubing
Ace Surgical suction tube #0034240 or equivalent

Vacuum source
Olympus Suction Pump Model KV-5 or equivalent

Vacuum canister
Bemis 3000cc Hi-Flow Canister Model 3002 055 or equivalent

NEW PRODUCT WARRANTY

Interlace Medical products are guaranteed to be free from defects in material and workmanship for one year beginning from date of invoice.

This limited warranty is restricted to repair or replacement by Interlace Medical, at its option, of any product found to be defective during the warranty period. Damage inflicted to a product by the user that causes it to be unsuitable for refurbishment may result in additional charges, regardless of warranty status. All warranties apply to the original buyer only. In no event shall Interlace Medical be liable for any anticipated profits, consequential damages or loss of time incurred by the buyer with the purchase or use of any product.
NO OTHER WARRANTY, EXPRESSED OR IMPLIED, IS GIVEN.

SERVICE WARRANTY

Service Replacement Units Warranty

The Interlace Medical Hysteroscopic Morcellation System replacement unit is warranted to be free from defects in material and workmanship for 90 days from the date of original invoice unless otherwise provided by local law.

EC	REP

European Representative
Street Address
City, Postal Code
Country

Service Replacement Program

Interlace Medical offers a 24-hour Service Replacement Program for its products to minimize downtown in your operating room. Our goal is to ship you a service replacement unit within 24 hours** of your call (during normal business hours). For a Return Authorization (RA) number or for additional information on this program, call Customer Service 1-508-875-1343 in the U.S., or contact your authorized representative.

**24-hour shipment is not offered in all countries

Repair Service Program

For devices no longer under warranty, repairs can be made by Interlace Medical or by an authorized agent. Non-warranty repairs will be made at the list price of replacement parts, plus labor. If requested, we will provide an estimate of repair cost and time required for the repair before any work is done. Repair items should be carefully repackaged, market with the Return Authorization (RA) number, and returned postpaid to the appropriate Interlace Medical Service Center. Interlace Medical Customer Service or your local authorized representative can provide shipping information.

The Interlace Medical Hysteroscopic Morcellation System and components are covered by one or more of the following U. S. Patent Numbers: patents pending

Interlace MEDICAL

REF 10-100

Contents – 1, Handpiece

Read Instructions Prior to Use

NON STERILE

Must be used with sterile drape

℞ only

XXXX-XX

SN XXXXXXX

CE XXXX

Manufactured for:
Interlace Medical
139 Newbury Street
Framingham, MA 01701
(508) 875-1343

EC REP

EU Rep Name
Street Address
City, Postal Code
Country

Patents Pending

02-001 Rev A