U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K081070 - 224 pages
COMPANY:	INTERLACE MEDICAL, INC. (INTEMEDIY)
PRODUCT:	HYSTEROSCOPE (AND ACCESSORIES) (HIH)
SUMMARY:	Product: INTERLACE MEDICAL OPERATIVE HYSTEROSCOPY SYSTEM
DATE REQUESTED:	Oct 5, 2015
DATE PRINTED:	Oct 5, 2015
Note:	Printed

K081070

Interlace Medical, Inc.
Operative Hysteroscopy System
510K Summary of Safety and Effectiveness JUL 23 2008
April 11, 2008

1. Sponsor Name

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

2. Device Name

Proprietary Name: Interlace Medical Operative Hysteroscopy System
Common/Usual Name: Hysteroscope and accessories

3. Identification of Predicate or Legally Marketed Device

The Interlace Medical Operative Hysteroscopy System is substantially equivalent to the Smith and Nephew Hysteroscope and Accessories cleared under K013870

4. Device Description

The Interlace Medical Operative Hysteroscopy System is intended for use in visualizing the uterine cavity and performing operative hysteroscopy procedures. The Operative Hysteroscopy System includes an obturator, a sheath and a hysteroscope. The obturator is used to facilitate introduction of the sheath into the uterine cavity. The single use sheath includes a working channel to permit the introduction of instrumentation. The reusable fiber optic hysteroscope is designed with optical lenses for visualization and optical fibers for illumination. The obturator is inserted into the working channel of the sheath and the hysteroscope is inserted into a designated lumen of the sheath. The Operative Hysteroscopy System can be combined with a hysteroscopic fluid management system (not the subject of this submission) to provide continuous flow hysteroscopy capability. The hysteroscope can be used with standard O.R. camera couplers.

5. Intended Use

Interlace Medical Operative Hysteroscopy System is used to provide viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

6. Comparison of Technological Characteristics

The Interlace Medical Operative Hysteroscopy 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 Medical Operative Hysteroscopy System has the same intended use and

technological characteristics as the predicate device, the Interlace Medical Operative Hysteroscopy System does not raise any new safety and efficacy concerns when compared to the similar legally marketed device.

The descriptive characteristics demonstrate that the Interlace Medical Operative Hysteroscopy System are substantially equivalent to the predicate device and is capable of safely and accurately performing the stated intended use.

7 Performance Testing
The Interlace Medical Operative Hysteroscopy System meets electrical safety standards.

8. Statement of Equivalency
The Interlace Medical Operative Hysteroscopy 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 Operative Hysteroscopy System has the same in intended use and technological characteristics as the predicate device, the Interlace Operative Hysteroscopy System does not raise any new safety and efficacy concerns when compared to the similar legally marketed device.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 2008

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

Re: K081070
Trade Name: Interlace Medical Operative Hysteroscopy System
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: June 13, 2008
Received: June 17, 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 (PMA), 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): TBD K081070

Device Name: Interlace Medical Operative Hysteroscopy System

Indications For Use:

Interlace Medical Operative Hysteroscopy System is used to provide viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

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 K081070

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): K081070/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

K081070 A1

FDA CDRH DMC

JAN 19 2011

Received

January 17, 2011

FDA CDRH DMC

JAN 19 2011

Received

K~~57~~0

K71

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 J. Vozella

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

Interlace MEDICAL

FDA CDRH DMC

JAN 19 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: K081070 - 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) #: K081070
Device Name: Interlace Medical Operative Hysteroscopy 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 MED CAL

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: K081070 - 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) #: K081070
Device Name: Interlace Medical Operative Hysteroscopy 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

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 2008

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

Re: K081070
Trade Name: Interlace Medical Operative Hysteroscopy System
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: June 13, 2008
Received: June 17, 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 (PMA), 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): TBD K081070

Device Name: Interlace Medical Operative Hysteroscopy System

Indications For Use:

Interlace Medical Operative Hysteroscopy System is used to provide viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

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 K081070

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2008

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

Re: K081070
Trade Name: Interlace Medical Operative Hysteroscopy System
Dated: April 11, 2008
Received: April 15, 2008

Dear Mr. Adams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following information.

Device Description

1. In section II you provided a description of the Interlace Medical Operative Hysteroscopy System. Please provide a more complete description/characterization of the device. Please provide the following parameters:
   - fiberoptic imaging system description (# fibers, fibers per sq. mm, size of fiber core, area of active fiber per mm^2)
   - distortion
   - percent of luminous energy transmitted

   Please indicate whether the hysteroscope has a tip articulation feature. Also, please indicate whether the field of view provided is for use in air or water.

Substantial Equivalence

2. In section III you compared characteristics of your system to the predicate device (Smith and Nephew Hysteroscope and Accessories – K013870). The predicate device that you have chosen has an optical design that uses a rod/lens whereas your system uses fiberoptics. Please provide an additional predicate device that uses fiberoptic technology comparable to the Interlace Medical Hysteroscope. Please provide a more comprehensive table that compares the characteristics of your device to the predicate devices. Please use the following example:

Characteristic	Interlace Medical Operative Hysteroscopy System	Predicate Device	Predicate Device
Dimensions			
Working Length			
Outer Diameter			
Working channel diameter			
Illumination			
Recommended light source			
Power rating of light source			
Optics			
Technology			
Depth of Field			
Direction of view			
Field of view in Air/Water			
Resolution			
Magnification			
Focal length			
Distortion			
# fibers			
Fibers per sq. mm			
Size of fiber core			
Area of active fiber per mm^2			
Pixel Count			
Thermal Specs.			
Max. Temp.			
Luminous energy transmitted			

Mechanics			
Tip Articulation			
Reusable or disposable			
How introduced			
RF Electrosurgical Features			

Labeling

3. You provided a copy of the Operating Manual in Attachment 1. There were deficiencies noted with respect to the indications, contraindications, warnings, and precautions. Please either make the following changes to the Operating Manual or provide a clinical justification for why they are not necessary:

    a. On page 32, please add the following sentence under Indications for Use: "Note: Hysteroscopes are used as tools for access to the uterine cavity and are not, in and of themselves, a method of surgery."

    b. On page 32, under Diagnostic Hysteroscopy, please add a bullet for" Intrauterine Foreign Body", delete "and pregnancy wastage", and add "or sonohysterogram" after "Evaluation of abnormal hysterosalpingogram."

    c. On page 32, under Operative Hysteroscopy, please add a bullet for "Endometrial Ablation", add the word "endometrial" before biopsy, and replace "Removal of submucous fibroids and large polyps" with "Polypectomy."

    d. On page 32 prior to "Contraindications to Hysteroscopic Myomectomy," please add the following section:

    Contraindications to Endometrial Ablation

    Hysteroscopic endometrial ablation, whether by laser or electrosurgery, should not be undertaken without adequate training, preceptorship, and clinical experience. Additionally, endometrial biopsy should be performed prior to any ablation. The following are clinical conditions that can significantly complicate hysteroscopic endometrial endometrial ablation:

    - Adenomatous Endometrial Hyperplasia
    - Uterine Leiomyoma
    - Severe Adenomyosis

- Pelvic Pain (Subtle PID)
- Uterine anomalies

e. On page 33, please change the title from "For Continuous Flow Hysteroscopy" to "For Continuous Fluid Flow Hysteroscopy" and please change the following text from:

> "If liquid distension medium is used, strict fluid intake and output surveillance should be maintained."

to:

> "If a liquid distension medium is used, strict fluid intake and output surveillance should be maintained to ensure that fluid deficit is known at all times. Depending on whether non-electrolyte or electrolyte solution is being used, when excessive fluid deficit occurs, consideration should be given to stopping further infusion and concluding the procedure".

f. On page 33, please change the title from "Potential Complications of Continuous Flow Hysteroscopy" to "Potential Complications of Continuous Fluid Flow Hysteroscopy" and add death to the list of potential complications.

g. Please add the following section after the section on potential complications of continuous fluid flow hysteroscopy:

For Continuous CO_2 Flow Hysteroscopy

If CO_2 gas is used as a distension medium, operative hysteroscopy is contraindicated due to the risk of gas embolization. CO_2 gas may be used for diagnostic procedures. It is extremely important that a hysteroscopic insufflator is used. Death has been reported when laparoscopic CO_2 insufflators were used during hysteroscopy. Flow of CO_2 should be limited to <100 mL/min, and intrauterine pressure should not exceed 100 mmHg.

Potential complications of Continuous flow hysteroscopy with CO_2:

- CO_2 embolization
- Circulatory collapse
- Death

h. On page 33, under Precautions, please add the following:

A thorough understanding of the principles and techniques involved in laser and

ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device and other medical instruments. Ensure that insulation or grounding is not compromised.

i. On page 33, please replace the current precaution wording regarding intrauterine fluid distension (second bullet) with the following:

Gravity fed intrauterine fluid distension can usually be accomplished with pressures in the rage of 35-75 mmHg. Hanging the fluid distention medium 42 inches above the patient can generate intrauterine pressure of approximately 80 mmHg. Unless the systemic blood pressure is excessive, it is seldom necessary to use pressures greater than 75-80 mmHg.

Cleaning and Sterilization

4. According to the guidance document, "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance (1996)", it is the responsibility of the original equipment manufacturer to provide the user with a cleaning and sterilization procedure that has been successfully validated. Although page 3 of your Operating Manual, briefly describes the cleaning process to be used on your device, the submission does not contain a description of how you validated this process. For devices that are reusable between multiple patients, cleaning validation studies should be conducted using organic soil containing hemoglobin, protein and/or carbohydrate. Therefore, please validate your cleaning method and provide a detailed description of the method used and results observed. Please note that your results should indicate the levels of hemoglobin, protein and/or total organic carbon on your device before and after cleaning.*

5. Similarly, you have not fully described how you validated your sterilization method, (citing the standard used is not adequate). Therefore, please provide a detailed description of your sterilization validation process. This description should include a load configuration diagram showing where the devices are placed in the ethylene oxide (EtO) chamber and "worst-case" placement of at least 10 biological indicators on each device. In addition, please provide your raw data results. (Note that you should use at least three of your devices, or appropriate Process Challenge Devices, in your validation process.)* Your Contract Sterilizer should be able to provide you with this information.

6. Please provide the name and address of the contract sterilizer for the sterile, single use sheath.

7. Please clearly and appropriately label each of the parts of your device as reusable (non-sterile, to be cleaned and sterilized prior to each use) or single-use only (sterile, discard after single-use).

8. You indicate that the sterilization residuals levels after sterilization are as follows: EtO ≤

20mg/day, Ethylene Chlorohydrin ≤ 12 mg/day. Please provide the exact values of these residuals.

9. You describe your device packaging as having a HDPE backing in a standard Tyvek/Mylar pouch. In addition, you indicate that, "the product will be labeled with an expiration date of 6 months from the date of sterilization and subsequently validated later to 2 years". However, you have not described the testing conducted to ensure that the sheath maintains its sterility for 6 months in "worst-case" storage conditions. Therefore, please provide descriptions of your package integrity and shelf life testing protocols used to provide this assurance.

   *For additional guidance on cleaning and sterilization of medical devices, you may refer to the following guidance documents that can be downloaded from the FDA website using the following link: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfggp/search.cfm

   - Updated 510(k) Sterility Review, Guidance K90-1; *Guidance for Industry and FDA; Document issued on: August 30, 2002)*
   - AAMI TIR30:2003 - A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices)
   - Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance (1996)
   - ANSI/AAMI/ISO 11135, 1994: Medical Devices-Validation and routine control of ethylene oxide sterilization.

Biocompatibility

10. On page 20 you provided a list of materials used in components either in the fluid path or in patient contact. Please provide more detailed descriptions of the patient contacting materials of the hysteroscope system including a drawing showing the location of the materials and the chemical abstract service numbers and manufacturers of the materials. Please indicate whether the patient contacting materials are identical to those used in the predicate devices and describe any colorants used. Also, please discuss whether there is possible interaction of the materials.

    Also, please provide a description of the relative amounts of the materials in the predicate devices to those in the hysteroscope system and describe the whether the materials have similar types of patient contact. If sufficient information is not supplied, then biocompatibility testing including system toxicity may be required.

Electrical Safety and Electromagnetic Compatibility Testing

11. You indicated on page 18 that the device meets the IEC 60601-2-18 standard for safety of endoscopic equipment. Please provide a copy of the test results showing the unit that was tested and the date of the report. Also, please provide the following leakage currents:
    - Enclosure leakage current
    - Patient leakage current

12. The submission does not address electromagnetic compatibility. Please either supply evidence of compliance with IEC 601-1-2 (or test results that guarantee a similar level of protection) or justify why this information is unnecessary.

Performance Testing

13. In section IV you provided information on safety for endoscopic equipment (IEC 60601-2-18), thermal safety, and optical resolution testing. You did not include a description of validation testing conducted on the product. Please provide a list of validation tests that are conducted on the product to ensure proper operation of the device.

14. Your submission indicates that the device will be used for both diagnostic and operative hysteroscopy. This means that the device must be used with an irrigation sleeve, laser equipment, and other ancillary instrumentation. Please provide specific descriptions of the ancillary equipment to be used with your hysteroscope for operative procedures. In addition, please describe what steps (including testing, if any) you have taken to ensure that these instruments are compatible with your hysteroscope.

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

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation

of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements" at www.fda.gov/cdrh/ode/guidance/1655.html.

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 additional information 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.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

If you have any questions concerning the contents of the letter, please contact Glenn Bell at (240) 276-4106. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Colin M Pollard

Colin M. Pollard
Chief, Obstetrics and Gynecology
Devices Branch
Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

MAY 15 2008

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
D.O.
Draft: 5-9-08 GBB
Revised: 5-13-08 GBB
Final:cdb:5.14.08

HFZ #	Last Name	Date	HFZ #	Last Name	Date	HFZ #	Last Name	Date
470	Bell	5/14/08						
Z470	Pollard	5/15/08						

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

April 16, 2008

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

510(k) Number: K081070
Received: 15-APR-2008
Product: INTERLACE MEDICAL OPERATIVE HYSTEROSCOPY 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, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1655.pdf. Please refer to this guidance for information on a formalized interactive review process. 2)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).

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

Site: null

K081070

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
D AND DRUG ADMINISTRATION
DICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade
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)
(b)(4)

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: ·//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)

[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD080131

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 POSES 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

142 K 39 OR II

Site: null

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION	
(b)(4)	11-Apr-2008

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

139 Newbury St
Framingham, MA 01701

April 11, 2008

FDA CDRH DMC

APR 15 2008

Received

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 Operative Hysteroscopy System

Dear Sir/Madam:

Pursuant to 21 CFR 807.90 Interlace Medical Incorporated, 139 Newbury St, Framingham, MA 01701 is submitting two copies of this 510(k) notification for the Interlace Medical Operative Hysteroscopy 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 Operative Hysteroscopy 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
Chief Technical Officer

Interlace Medical Inc.
Operative Hysteroscopy System
Premarket Notification

TABLE OF CONTENTS

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)
4/11/2008	(b)(4) Trade	

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	Establishment Registration Number *(if known)*		
Interlace Medical Inc	TBD		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	(508) 875.1343		
Street Address	FAX Number *(including area code)*		
139 Newbury St	(508) 370.8026		
City	State / Province	ZIP/Postal Code	Country
Framingham	MA	01701	US
Contact Name			
Ron Adams			
Contact Title	Contact E-mail Address		
CTO	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			
ontact Title	Contact E-mail Address		

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)

- ☒ 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

☒ 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	K013870	1	Hysteroscope and Accessories	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 Operative Hysteroscopy 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

☒ 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 ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Obstetrics/Gynecology

Indications *(from labeling)*

Interlace Medical Operative Hysteroscopy System is used to provide viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

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

☐ Manufacturer ☐ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name: (b)(4) Trade Secret

Establishment Registration Number: (b)(4)

Division Name *(if applicable)*

Phone Number *(including area code)*: (b)(4) Trade Secret Process - Product

Street Address: (b)(4) Trade Secret Process - Product Specification

FAX Number *(including area code)*: ( )

City: (b)(4) Trade

State / Province: (b)(4) Trade

ZIP Code: (b)(4) Trade

Country: (b)(4) Trade

Contact Name: (b)(4) Trade Secret Process

Contact Title: (b)(4) T d

Contact E-mail Address: (b)(4) Trade Secret Process - Product

---

☒ Original ☐ Add ☐ Delete

FDA Establishment Registration Number: (b)(4) T d

☐ Manufacturer ☒ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name: (b)(4) Trade Secret Process - Product Specification

Establishment Registration Number: (b)(4) Trade S t

Division Name *(if applicable)*

Phone Number *(including area code)*: (b)(4) Trade Secret Process - Product Specification

Street Address: (b)(4) Trade Secret Process - Product Specification

FAX Number *(including area code)*: ( )

City: (b)(4) Trade Secret Process - Product

State / Province: (b)(4) Trade

ZIP Code: (b)(4) Trade Secret

Country: (b)(4) Trade

Contact Name: (b)(4) Trade Secret Process

Contact Title: (b)(4) Trade

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	60601-2-18	IEC/EN	Medical electrical equipment -- Part 2: Particular requirements for the safety of endoscopic equipment	1996	
	Standards No.	Standards Organization	Standards Title	Version	Date
2	11135	ISO	Medical Devices-Validation and routine control of ethylene oxide sterilization.	1994	
	Standards No.	Standards Organization	Standards Title	Version	Date
3					
	Standards No.	Standards Organization	Standards Title	Version	Date
4					
	Standards No.	Standards Organization	Standards Title	Version	Date
5					
	Standards No.	Standards Organization	Standards Title	Version	Date
6					
	Standards No.	Standards Organization	Standards Title	Version	Date
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

...t 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

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 06-30-2008

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

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

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Interlace Medical Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
04/11/2008

3. ADDRESS *(Number, Street, State, and ZIP Code)*
139 Newbury St
Framingham, MA 01701

4. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 508.875.1343
(Fax) 508.370.8026

PRODUCT INFORMATION

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

Proprietary Name: Interlace Medical Hysteroscope and Sheath

Common/Classification Name: Hysteroscope and accessories

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

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

CERTIFICATION STATEMENT / INFORMATION

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

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

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

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

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

NCT Number(s):

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

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11
(Name) Ron Adams
(Title) Chief Technical Officer

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)*
139 Newbury St
Framingham, MA 01701

14. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 508.875.1343
(Fax) 508.370.8026

15. DATE OF CERTIFICATION
04/11/2008

PSC Graphics (301) 113-6526 14

000006 152

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.	Present	
Table of Contents.	Present	
Truthful and Accurate Statement.	Page 00013	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	Page 00013	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	Page 00013	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510(k)] Manual.	Page 00013	
Statement of Indications for Use that is on a separate page in the premarket submission.	Page 00011	
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 00016	
510(k) Summary or 510(k) Statement.	Page 00067	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	Page 00038	
Identification of legally marketed predicate device. *	Page 00016	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	Page 00013	
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 020	
b) Sterilization and expiration dating information:	Page 019	
i) sterilization process	Page 019	
ii) validation method of sterilization process	Page 019	
iii) SAL	Page 019	
iv) packaging	Page 019	
v) specify pyrogen free	NA	
vi) ETO residues	Page 019	
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

Indications for Use

510(k) Number (if known): TBD K081070

Device Name: Interlace Medical Operative Hysteroscopy System

Indications For Use:

Interlace Medical Operative Hysteroscopy System is used to provide viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

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)

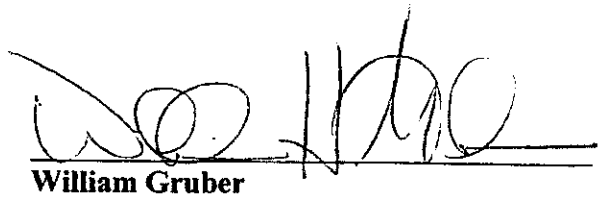
Concurrence of CDRH, Office of Device Evaluation (ODE)

000014

157

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

April 11, 2008

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 Operative Hysteroscopy 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 Operative Hysteroscopy System can be found in Attachment 1.

Section II Device Description

The Interlace Medical Operative Hysteroscopy System is intended for use in visualizing the uterine cavity and performing operative hysteroscopy procedures. The Operative Hysteroscopy System includes an obturator, a sheath and a hysteroscope. The obturator is used to facilitate introduction of the sheath into the uterine cavity. The single use sheath includes a working channel to permit the introduction of instrumentation. The reusable fiber optic hysteroscope is designed with optical lenses for visualization and optical fibers for illumination. The obturator is inserted into the working channel of the sheath and the hysteroscope is inserted into a designated lumen of the sheath. The Operative Hysteroscopy System can be combined with a hysteroscopic fluid management system (not the subject of this submission) to provide continuous flow hysteroscopy capability. The hysteroscope can be used with standard camera couplers.

The Interlace Medical Operative Hysteroscopy System is a flexible fiberoptic scope which functions by light being transmitted from a standard external high intensity light source through illumination fibers to the distal tip of the scope. The image is transmitted via an imaging bundle to an eyepiece. The image is viewed directly or transmitted through a video camera to a monitor. The Interlace Medical Hysteroscope is used with any standard off the shelf light source.

Device Configuration and Materials

Hysteroscope:

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

Sheath:

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

Packaging and Sterilization/Disinfection

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

Section III. Substantial Equivalence

Interlace Medical Operative Hysteroscopy System is substantially equivalent to:

- Smith and Nephew Hysteroscope and Accessories cleared under K013870

The following table identifies the similarities and differences between the Interlace Medical Operative Hysteroscopy System and its predicate.

Characteristic	**Interlace Medical Operative Hysteroscopy System**	**Smith and Nephew Hysteroscope and Accessories**
510K Number	Proposed	K013870
Indications	To provide viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.	To permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures

(b)(4) Trade Secret Process - Product 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 to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.

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 to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.

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.

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 Medical Operative Hysteroscopy 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 Medical Operative Hysteroscopy System has the same intended use and technological characteristics as the predicate device, the Interlace Medical Operative Hysteroscopy System does not raise any new safety and efficacy concerns when compared to the similar legally marketed device.

The descriptive characteristics demonstrate that the Interlace Medical Operative Hysteroscopy System are 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 Operative Hysteroscopy System meets the following standard:

- IEC/EN 60601-2-18:1996 - Medical electrical equipment -- Part 2: Particular requirements for the safety of endoscopic equipment

The applicable standards data forms are included in Attachment 4A.

The following tests have been conducted

- Thermal Safety Testing per IEC 60601-2-18
- Optical resolution test

The optical results indicate that the Interlace Medical Operative Hysteroscopy System provide image resolution adequate for diagnostic and therapeutic hysteroscopy. In addition the results of the thermal safety testing indicated that in no instance did the temperature of the scope exceed the IEC 60601-2-18 limit of 50°C.

A summary of the testing and results is included in attachment 4B.

Section V: Sterilization and Biocompatibility

Scope:
The Interlace Hysteroscope is provided non sterile and intended to be sterilized by the user prior to use. The sterilization method is recommended as ETO.

Sterilization and cleaning instructions are included in the package insert found in Appendix 1. The instructions for reprocessing the device using the above methods is subject to validation according to ISO 17664:2004 Sterilization of Medical Devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices and the AAMI TIR 12-2004 "Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Manufacturers".

Sheath and Obturator:
The sheath will be provided sterile and 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 sheath 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.

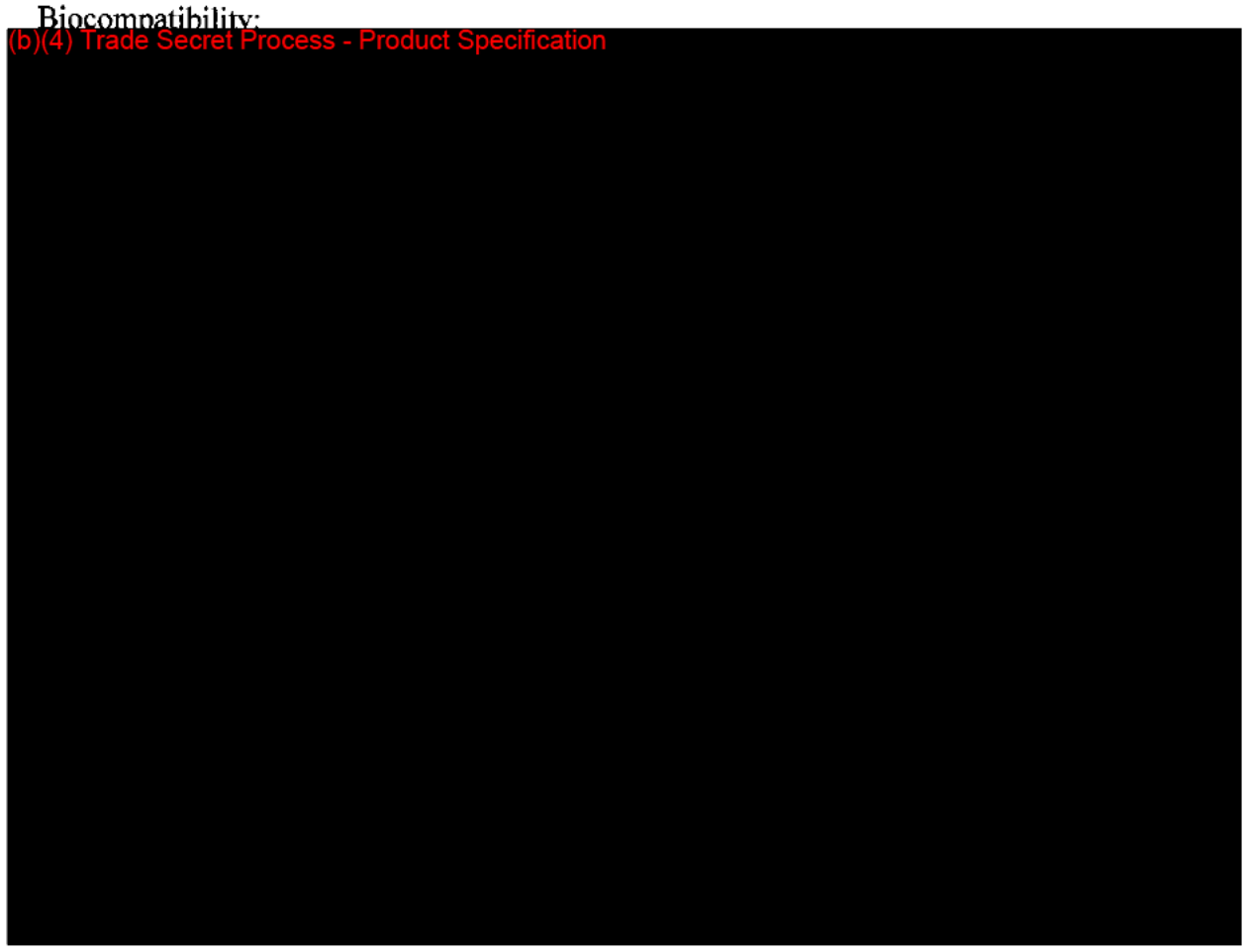
Ethylene oxide:	25 ppm
Ethylene chlorohydrin:	250 ppm
Ethylene glycol:	250 ppm

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

Biocompatibility:

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



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. Standards Data Form, Performance Data
5. 510K Summary of Safety and Effectiveness

ATTACHMENT 1

LABELING AND INSTRUCTIONS FOR USE

DEVICE LABELS – UNIT AND BOX

Interlace MEDICAL

REF 40-100

Contents – 1, Fiber Scope

Read Instructions Prior to Use

Rx only

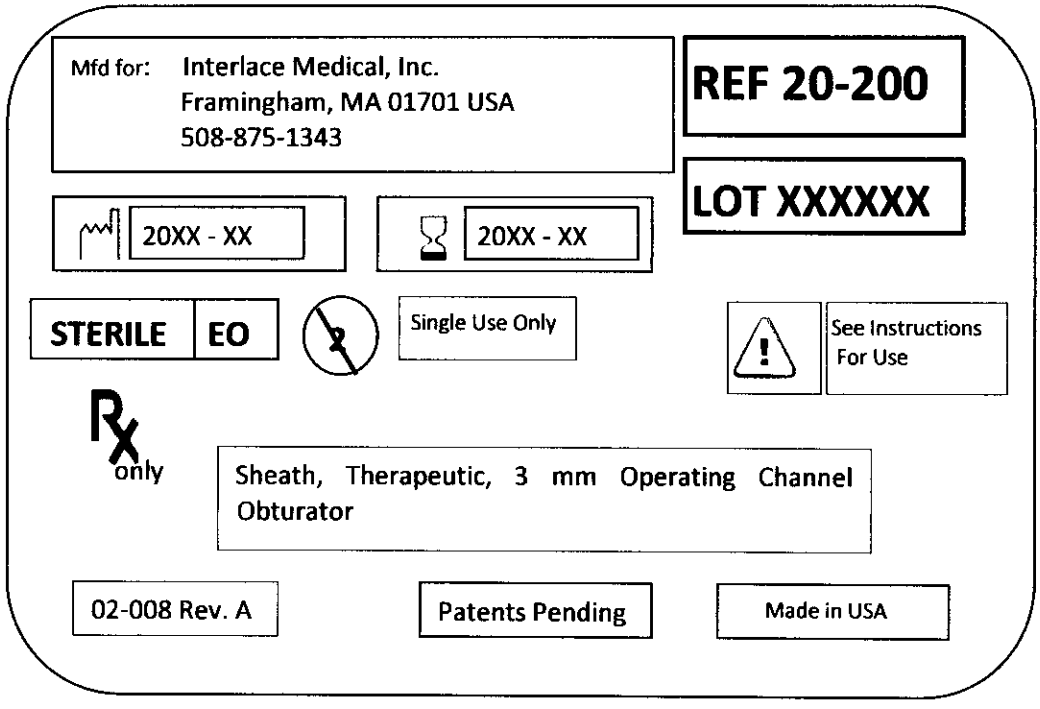
NON STERILE **Must be sterilized before use**

XXXX-XX LOT XXXXXXX

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

Patents Pending

02-009 Rev A


Mfd for: Interlace Medical, Inc.
Framingham, MA 01701 USA
508-875-1343
REF 20-200
LOT XXXXXX
20XX - XX
20XX - XX
STERILE EO
Single Use Only
See Instructions For Use
Rx only
Sheath, Therapeutic, 3 mm Operating Channel Obturator
02-008 Rev. A
Patents Pending
Made in USA

Interlace MEDICAL

REF 20-200

Contents – Sheath (Therapeutic – 3 mm working channel); Obturator

Read Instructions Prior to Use

℞ only STERILE EO

Single Use Only

XXXX-XX LOT XXXXXXX

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

Patents Pending

02-007 Rev A

INSTRUCTIONS FOR USE

Interlace Medical

Operative Hysteroscopy System

Interlace™
MEDICAL

177

Device Description

The Interlace Medical Operative Hysteroscopy System is intended for use in visualizing the uterine cavity and performing operative hysteroscopy procedures. The Operative Hysteroscopy System includes an obturator, a sheath and a hysteroscope. The obturator is used to facilitate introduction of the sheath into the uterine cavity. The single use sheath includes a working channel to permit the introduction of instrumentation. The reusable fiber optic hysteroscope is designed with optical lenses for visualization and optical fibers for illumination. The obturator is inserted into the working channel of the sheath and the hysteroscope is inserted into a designated lumen of the sheath. The Operative Hysteroscopy System can be combined with a hysteroscopic fluid management system to provide continuous flow hysteroscopy capability.
The hysteroscope can be used with standard camera couplers.

Indications for Use

Interlace Medical Operative Hysteroscopy System is used to provide viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

Diagnostic Hysteroscopy

- Abnormal uterine bleeding
- Infertility and pregnancy wastage
- Evaluation of abnormal hysterosalpingogram
- Amenorrhea
- Pelvic Pain

Operative Hysteroscopy

- Directed biopsy
- Removal of submucous fibroids and large polyps
- Submucous Myomectomy (see Contraindications)
- Transection of intrauterine adhesions
- Transection of intrauterine septa

Contraindications

- Acute pelvic inflammatory disease

Hysteroscopy may also be contraindicated by the following conditions, depending on their severity or extent:

- Inability to distend uterus
- Cervical stenosis
- Cervical/vaginal infection
- Uterine bleeding or menses
- Known pregnancy
- Invasive carcinoma of the cervix
- Recent uterine perforation
- Medical contraindication or intolerance to anesthesia

Contraindications to Hysteroscopic Myomectomy

Hysteroscopic myomectomy should not be undertaken without adequate training, preceptorship, and clinical experience. The following are clinical conditions that can significantly complicate hysteroscopic myomectomy:

- Severe anemia
- Inability to circumnavigate a myoma due to myoma size (e.g., predominantly intramural myomas with small submucous components).

Warnings

- **For use only by physicians trained in hysteroscopy**
- **Do not use with High Frequency Electrosurgical devices**
- **Suspicion of pregnancy should suggest a pregnancy test before the performance of diagnostic hysteroscopy.**
- **The hysteroscope is shipped non-sterile. It must be thoroughly cleaned and sterilized according to validated infection control procedures before use/reuse. If scope light post**

adapters have been used, they need to be disassembled, cleaned, and sterilized before every subsequent use.

- **Uterine perforation can result in possible injury to bowel, bladder, major blood vessels and ureter.**

For Continuous Flow Hysteroscopy:

- **If liquid distention medium is used, strict fluid intake and output surveillance should be maintained.**

Potential Complications of Continuous Flow Hysteroscopy:

Hyponatremia
Hypothermia
Pulmonary edema
Cerebral edema

- **High energy radiated light emitted from illuminating fiber at the distal end of the scope may give rise to temperatures exceeding 106° F/41° (within 8 mm in front of the scope). Do not leave tip of scope in direct contact with the patient tissue or combustible materials, as burns may result. Lower the light source output when working in close proximity to the object.**

- **The hysteroscope light post and adaptor may exceed temperatures of 41° C. Hysteroscopes should not be placed on the patient or on combustible materials, as burns may result.**

- **To prevent potential safety hazard to the patient caused by accidental loss of function of the device (i.e., front end damage by surgical instruments) it is recommend to have an additional sterile "stand-by" device during surgical procedures.**

- **Hysteroscopes can not be autoclaved. Autoclaving of scopes may result in irreparable damage. Low temperature sterilization methods or soaking disinfectant sterilization must be utilized.**

- **When scopes are used with laser equipment, appropriate filtering spectacles must be worn by the operating team. In some cases, a specific filter must be put between the scope and camera head to prevent camera damage by high-power laser radiation. Contact your laser supplier for details. To prevent scope damage by high-power laser radiation, always ensure that the laser delivery fiber is seen through the scope and not directed at the scope before energizing the laser.**

Precautions

℞

U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

- Vaginal ultrasonography before hysteroscopy may identify clinical conditions that will alter patient management.

- Intrauterine distension can usually be accomplished with pressure in the range of 35-75 mmHg. Unless the systemic blood pressure is excessive, it is seldom necessary to use pressures greater than 75-80mmHg.

- Prior to use, examine the device(s) for possible damage to assure proper functioning. If damaged, do not use.

- Avoid exposing the scope to sudden temperature changes. Do not immerse hot scopes into cold water or liquid.

Inspection Prior to Use

Prior to each use, the outer surface of the insertion portion of the hysteroscope should be inspected to ensure there are no unintended rough surfaces, sharp edges or protrusions.

Hysteroscope System Setup Instructions

The Interlace Medical Operative Hysteroscopy system consists of a sheath, obturator and hysteroscope as shown in Figure 1.

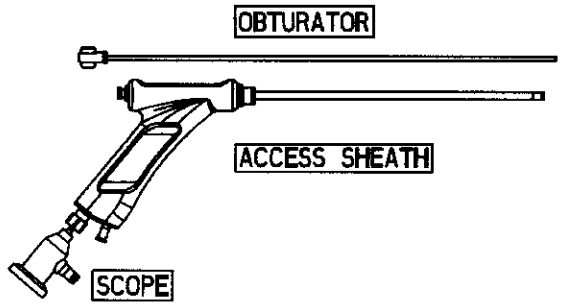


Figure 1. Hysteroscopy System

To place hysteroscope into sheath:

Insert the hysteroscope into the sheath, placing the light post of the hysteroscope into the slot of the sheath handle. Rotate the cam lock down to lock the scope in place. Reverse this process to remove the hysteroscope.

To place obturator into sheath:

Insert the obturator into the sheath utilizing the working channel of the sheath. Reverse this process to remove the obturator.

Sterilization

Hysteroscopes can not be autoclaved. Autoclaving of scopes may result in irreparable damage. Low temperature sterilization methods or soaking disinfectant sterilization must be utilized.

Hysteroscopes should be sterilized in a container which secures the instrument in place. Be sure the flexible shaft does not experience any undue forces or stress which can damage the delicate internal optics.

Sterilize the hysteroscope with ethylene oxide (Et0) gas, or other institution validated methods.

Ethylene Oxide (100% EtO) – wrapped)

Follow standard hospital procedure maintaining the following parameters:

Temperature:	131° ± 5° F (55° C)
Relative Humidity:	35-70%
Gas Concentration:	~ 736 mg/l
Exposure Time:	60 minutes
Aeration Time:	11 Hours

IMPORTANT: It is recommended that the institution employs procedures which include the use of biological indicators in order to determine the effectiveness of the sterilization process.

Hysteroscope Cleaning Instructions

Proper cleaning should be performed prior to sterilization.

- Light post adaptors must be removed prior to cleaning.
- Scrub all crevices using a cleaning brush to remove any visible debris from all crevices, taking care not to scratch any optical surface.
- Hysteroscopes should be soaked in an enzymatic, neutral pH cleaner for five minutes.
- Thoroughly rinse the scope to completely remove the cleaning solution.
- The scope has three optical surfaces that must be thoroughly cleaned and checked routinely to ensure both maximum transmission of illumination and a high-quality image.

  These are:

- The distal tip
- The proximal window or eyepiece
- The fiber optic light post

Removing Deposits from Scope Optical Surfaces

The aluminum oxide powder (REF XXXXX) is provided as an accessory to Interlace Medical scopes and is intended to be used, when required, to remove deposits on optical surfaces, thus maintaining optical integrity and allowing the scopes to perform as per their intended uses.

Note: Cleaning with aluminum oxide powder should only be performed when the image as viewed through the scope is cloudy, and not as part of your routine cleaning procedures.

To remove deposits, moisten a cotton-tipped swab with water. Dip the moistened swab into the aluminum oxide powder. Position the swab tip against the optical surface or the scope to be cleaned. While applying gentle pressure to the swab, scrub the window to remove any deposits. For smaller windows, rotate the swab instead of scrubbing. Rinse the optical surface with tap water and brush with a soft bristle brush while under running water to remove the aluminum oxide powder.

Note: Do not use any ultrasonic cleaning methods. The energy transmitted through fluid cavitations will damage seals and optical surfaces and will void the warranty.

Note: Foreign matter remaining on the fiber surface of the light post after cleaning may tend to burn and discolor the surface when exposed to a high intensity light source.

Hysteroscope Assembly/Disassembly Instructions

Interlace Medical Operative Hysteroscopes are compatible with Metal-Halide and Xenon light sources with up to 300 watts of power.

Place the correct adaptor on the light post of the fiber optic scope and on the instrument end of the light guide. Adapters are available for connection to Storz, Olympus, Wolf, and ACMI light sources as shown in Figure 2.

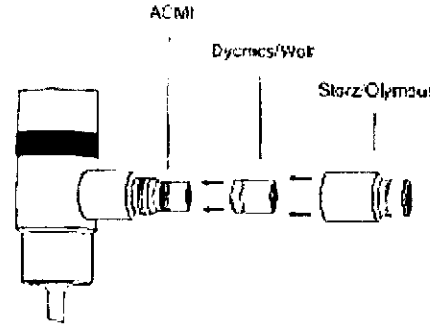


Figure 2 Light Post Adapters

The light post threads may be lubricated as needed, being sure to remove any excess lubricant as required. Make sure that the fiber optic surface remains free of foreign matter. Do not use tools to tighten the adapters – hand tighten only.

Maintenance

We recommend that you inspect the hysteroscope carefully before and after the procedure for possible signs of damage.

First, check the image quality of the scope by viewing the monitor. If image quality is impaired:

- Check the distal and proximal lenses of the hysteroscope for cracked or scratched lenses.
- Check the surface cleanliness of the distal and proximal lenses. A foggy or cloudy image can be the result of moisture entering the optical system or lack of cleanliness of exterior surfaces. When viewing reflected light, the surfaces should appear smooth and shiny

As a second step, check the illumination system of the scope. Reduced brightness can result from fiber damage:

- Check for fiber optic damage in the scope by holding the distal end of the scope toward a light and observing the light post on the hub. The center of the light post should appear clear or white. Noticeable black spots indicate serious damage to the fiber illumination bundle in the scope. This will affect light transmission and the brightness of the image viewed on the monitor.

- Check the light cable for damaged fibers by holding one end of the cable toward a light and observing the other end. Broken fiber will appear as black spots in the light field. A damaged light cable will affect its ability to transmit light and the brightness of the image viewed on the monitor.

Storage

Interlace Medical Hysteroscopes should be stored either in their shipping box or in a sterilization tray. In either case, proper care should be taken to ensure that the hysteroscope is immobile to prevent any damage.

New Product Warranty

The Interlace Medical Hysteroscopy System 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.

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 Program

Interlace Medical offers a 24-hour Service Replacement Program for its products to minimize downtime 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

FOR FURTHER INFORMATION

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

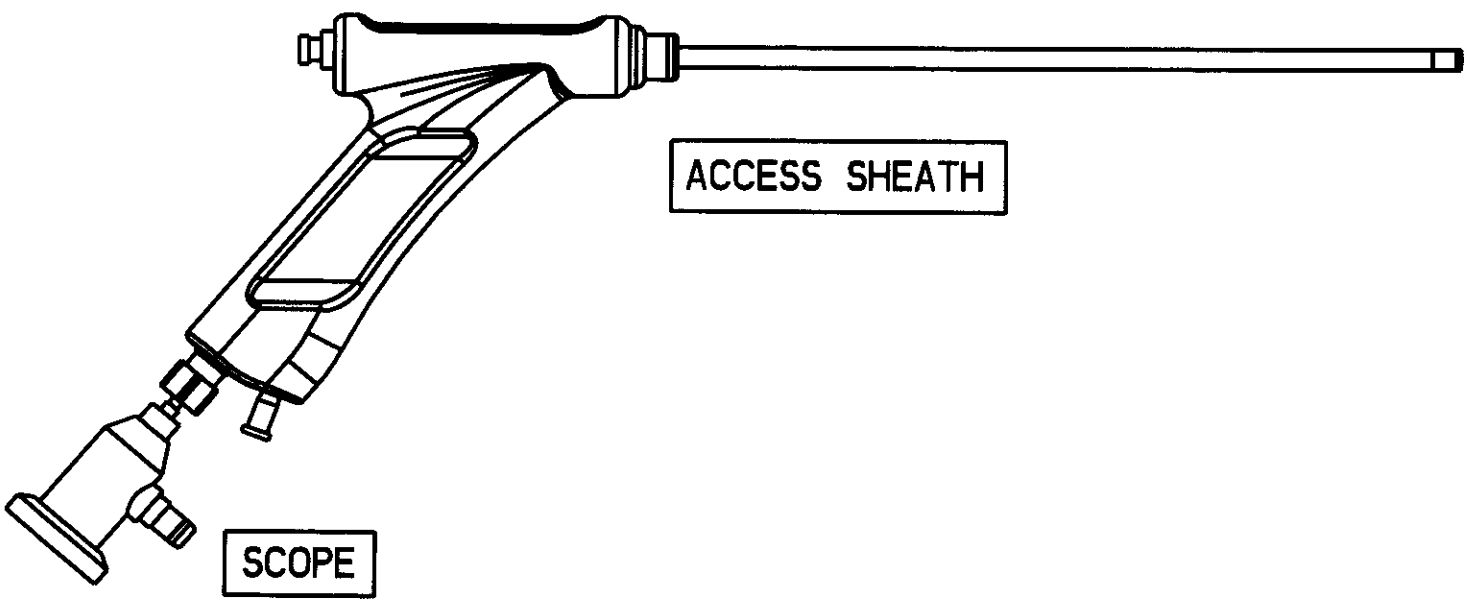
EC	REP

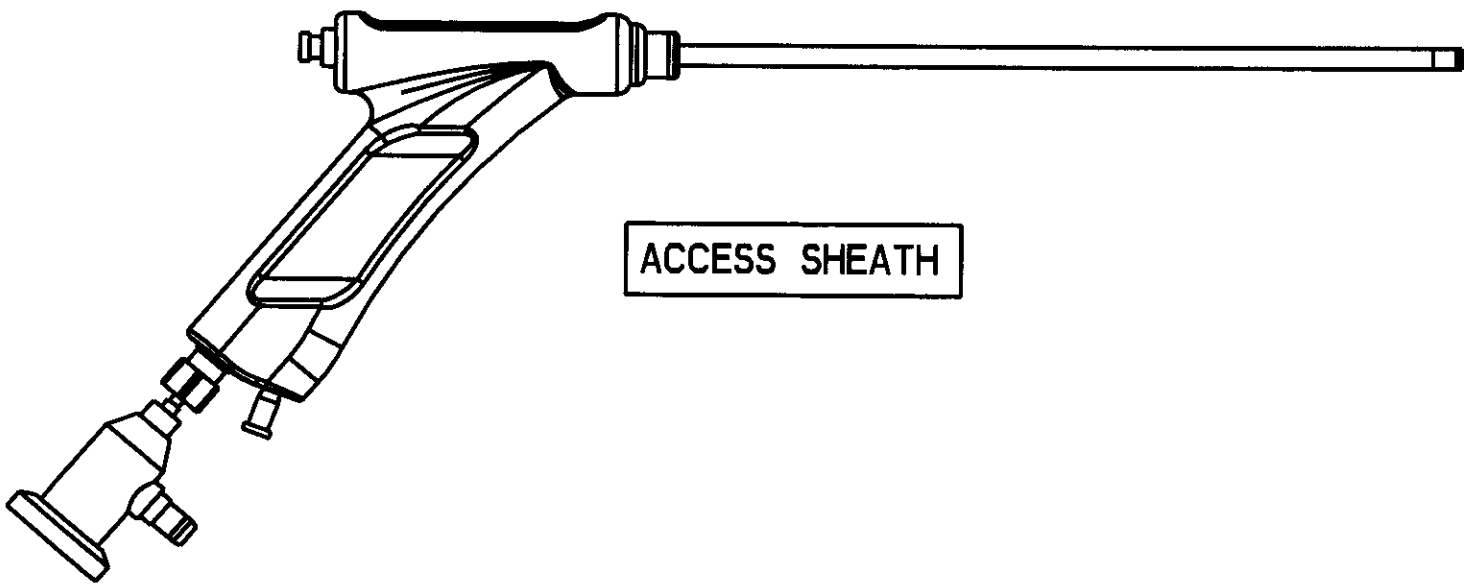
European Representative
Street Address
City, Postal Code
Country

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

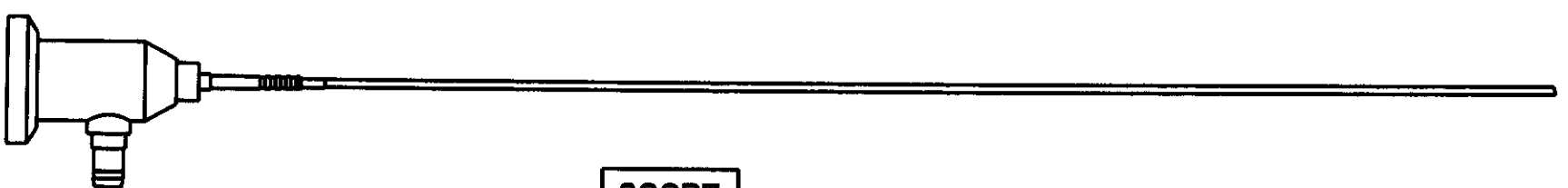
ATTACHMENT 2

DEVICE DRAWINGS


ACCESS SHEATH
SCOPE



ACCESS SHEATH



SCOPE

OBTURATOR
ACCESS SHEATH
SCOPE

(b)(4) Trade Secret Process - Engineering Drawings

(b)(4) Trade Secret Process - Engineering Drawings

ATTACHMENT 3

PREDICATE DEVICE LABELING AND INFORMATION

K013870
Page 1 of 2

JAN 17 2002

510(k) Summary
Smith & Nephew Operative Hysteroscope and Accessories
Date Prepared:

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

A. Submitter

Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, MA 01810

B. Company Contact

Janice Haselton
Regulatory Affairs Specialist

C. Device Name

Trade Name:	Smith & Nephew Operative Hysteroscope and Accessories
Common Name:	Hysteroscope
Classification Name:	Hysteroscopes and Accessories

D. Predicate Devices

Smith & Nephew's Images Hysteroscopes and Accessories K 971188
Richard Wolf's Hysteroscopes Operating Sheath and Insert K 000673

E. Description of Device

The proposed Smith & Nephew Operative Hysteroscope and Accessories is a reusable surgical device that incorporates a working channel into the needle portion of the hysteroscope. A reusable continuous flow sheath and blunt obturator are offered for atraumatic insertion through the uterine cervix.
The needle portion of the hysteroscope has an oval configuration to accommodate adequate fluid flow between the sheath and hysteroscope. The working channel is D-shaped to accommodate the fiber bundles and optical train in the needle.
The Smith & Nephew Operative Hysteroscope is compatible with the ETO and autoclave sterilization process. The device accessories can be autoclaved for reuse.

191

K013870
Page 3 of 12

D. Intended Use

The Smith & Nephew Operative Hysteroscope and Accessories are used to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures

E. Comparison of Technological Characteristics

Smith & Nephew's Operative Hysteroscope and accessories is substantially equivalent in design, materials of construction, function and intended use to the Smith & Nephew Images Hysteroscopes and accessories and the Richard Wolf operative Hysteroscopes. The changes in geometry do not introduce any new risks to the proposed device.

Janice Haselton

Janice Haselton

Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2002

Ms. Janice Haselton
Regulatory Affairs Specialist
Smith & Nephew, Inc.
160 Dascomb Road
ANDOVER MA 01810

Re: K013870
Trade/Device Name: Smith & Nephew Operative Hysteroscope and Accessories
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: 85 HIH
Dated: November 19, 2001
Received: November 21, 2001

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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

K960045
194

510(k) Number : K013870

Device Name : Smith & Nephew Operative Hysteroscope and Accessories

Indications for Use:

The Smith & Nephew Operative Hysteroscope and accessories are used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.

(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter ____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013870

195

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

smith&nephew

Smith & Nephew Operative Hysteroscope

OP-Hysteroskop von Smith & Nephew

Histeroscopio quirúrgico de Smith & Nephew

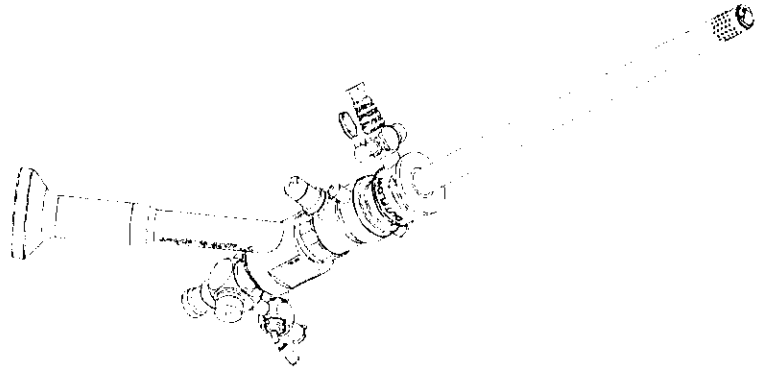
Hystéroscope interventionnel de Smith & Nephew

Isteroscopio operativo Smith & Nephew

Smith & Nephew operationshysteroskop

Smith & Nephew operatieve hysteroscoop

Smith & Nephew operasjonshysteroskop



Made in USA

CE 0123

196

Device Description

The Smith & Nephew Operative Hysteroscope is a reusable instrument for use in visualizing the uterine cavity and performing operative hysteroscopy. The hysteroscope is designed with optical lenses, optical fibers for illumination, and a working channel to permit introduction of instrumentation. The Operative Hysteroscope Set includes an obturator, outer sheath, and operative hysteroscope. The obturator is used to facilitate introduction of the sheath into the uterine cavity. The hysteroscope is inserted into the sheath. The Operative Hysteroscope Set combined with the Hysteroscopic Fluid Management System can provide continuous flow. The hysteroscope can be used with standard O.R. camera couplers.

Indications for Use

Smith & Nephew Operative Hysteroscopes are used to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

Diagnostic Hysteroscopy

- Abnormal uterine bleeding
- Infertility and pregnancy wastage
- Evaluation of abnormal hysterosalpingogram
- Amenorrhea
- Pelvic pain

Operative Hysteroscopy

- Directed biopsy
- Removal of submucous fibroids and large polyps
- Submucous myomectomy (see CONTRAINDICATIONS)
- Transection of intrauterine adhesions
- Transection of intrauterine septa
- Endometrial ablation (see CONTRAINDICATIONS)

Contraindications

- Acute pelvic inflammatory disease

Hysteroscopy may be contraindicated by the following conditions, depending on their severity or extent:

- Inability to distend uterus
- Cervical stenosis
- Cervical/vaginal infection
- Uterine bleeding or menses
- Known pregnancy
- Invasive carcinoma of the cervix
- Recent uterine perforation
- Medical contraindication or intolerance to anesthesia

Contraindications to Endometrial Ablation:

Hysteroscopic endometrial ablation, whether by laser or electrosurgery, should not be undertaken without adequate training, preceptorship, and clinical experience. Additionally, endometrial biopsy should be performed prior to any ablation. The following clinical conditions can significantly complicate hysteroscopic endometrial ablation:

- Adenomatous endometrial hyperplasia
- Uterine leiomyoma
- Severe adenomyosis
- Pelvic pain (subtle PID)
- Uterine anomalies

Contraindications to Hysteroscopic Myomectomy:

Hysteroscopic myomectomy should not be undertaken without adequate training, preceptorship, and clinical experience. The following clinical conditions can significantly complicate hysteroscopic myomectomy:

- Severe anemia
- Inability to circumnavigate a myoma due to myoma size, e.g., predominantly intramural myomas with small submucous components.

⚠ Warnings

- This product is shipped non-sterile. It must be disassembled and sterilized before the first use. It must be disassembled, cleaned, and sterilized before every subsequent use.
- 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.
- Suspicion of pregnancy should suggest a pregnancy test before the performance of diagnostic hysteroscopy.

For Continuous Flow Hysteroscopy:

If liquid distention medium is used, strict fluid intake and output surveillance should be maintained. Intrauterine instillation exceeding 1 liter should be followed with great care to prevent the possibility of fluid overload.

Potential Complications of Continuous Flow Hysteroscopy:

Hyponatremia

Hypothermia

Uterine perforation resulting in possible injury to bowel, bladder, major blood vessels and ureter

Pulmonary edema

Cerebral edema

- High energy radiated light emitted from illuminating fiber at the distal end of the scope may give rise to temperatures exceeding 106° F/41° C (within 8 mm in front of the scope). Do not leave tip of scope in direct contact with patient tissue or combustible materials, as burns may result. Lower the light source output when working in close proximity to the object.
- The hysteroscope light post and adaptor may exceed temperatures of 106° F/41° C. Hysteroscopes should not be placed on the patient or on combustible materials, as burns may result.
- To prevent potential safety hazard to the patient caused by accidental loss of function of the device (i.e., front end damage by surgical instruments) it is recommended to have an additional sterile "stand-by" device during surgical procedures.
- When using HF surgical equipment, keep the working part of the active electrode in the field of view to avoid accidental HF burns. Avoid contact with metal parts of the scope and other conductive accessories by ensuring before activation of the HF output that the active electrode is at a sufficient distance from the tip of the scope. Ensure that only medical electrical equipment that complies with IEC 60601-1 and its relative particular standards is connected to, or used in conjunction with, the scope.
- Vaginal ultrasonography before hysteroscopy may identify clinical conditions that will alter patient management.
- When scopes are used with laser equipment, appropriate filtering spectacles must be worn by the operating team. In some cases, a specific filter must be put between the scope and camera head to prevent camera damage by high-power laser radiation. Contact your laser supplier for details. To prevent scope damage by high power laser radiation, always ensure that the laser delivery fiber is seen through the scope and not directed at the scope before energizing the laser.

Precautions

℞ 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.
- Intrauterine distension can usually be accomplished with pressures in the range of 35–75 mmHg. Unless the systemic blood pressure is excessive, it is seldom necessary to use pressures greater than 75–80 mmHg.
- Not all hysteroscopes can be autoclaved. Those that can are clearly marked as autoclavable on their proximal end. Autoclaving scopes for which this was not intended may result in irreparable damage.
- Avoid exposing the scope to sudden temperature changes. Do not immerse hot scopes into cold water or liquid. Allow the scope to properly cool after autoclave cycles.
- Any mechanical manipulation of the eyepiece may result in seal breakage, therefore do not attempt to remove the eyepiece.

198

Inspection Prior to Use

Prior to each use, the outer surface of the insertion portion of the hysteroscope and, if applicable, the inner surface of the working channel, should be inspected to ensure there are no unintended rough surfaces, sharp edges or protrusions.

Note: Match the blue ring on the hysteroscope's inflow stopcock to the blue luer connector on the appropriate inflow tubing.

Maintenance

We recommend that you inspect the endoscope carefully before and after the procedure for possible signs of damage. This will allow immediate detection of minor damage, which if repaired immediately will increase the life of your investment.

First, check the image quality of the scope by viewing the monitor. If image quality is impaired:

- Check the distal and proximal lenses of the endoscope for cracked or scratched lenses.
- Inspect the shaft of the endoscope to detect any noticeable dents. Dents along the shaft might cause lenses inside the tube to crack.
- Check the surface cleanliness of the distal and proximal lenses. A foggy or cloudy image can be the result of moisture entering the optical system or lack of cleanliness of exterior surfaces. When viewing reflected light, the surfaces should appear smooth and shiny. For autoclavable scopes, specific instructions to remove deposits are provided below.

As a second step, check the illumination system of the scope. Reduced brightness can result from fiber damage:

- Check for fiber optic damage in the scope by holding the distal end of the scope toward a light and observing the light post on the hub. The center of the light post should appear clear or white. Noticeable black spots indicate serious damage to the fiber optic bundle in the scope. This will affect light transmission and the brightness of the image viewed on the monitor.
- Check the light cable for damaged fiber optics by holding one end of the cable toward a light and observing the other end. Broken fibers will appear as black spots in the light field. A damaged light cable will affect its ability to transmit light and the brightness of the image viewed on the monitor.

WARNING: Hysteroscopes are supplied non-sterile. They must be sterilized before the first use. They must be disassembled, cleaned, and sterilized before every subsequent use.

Cleaning Instructions

Proper cleaning should be performed prior to sterilization.

- Light post adaptors **must** be removed prior to cleaning.
- Rubber boot **must** be removed prior to cleaning.
- Sheath **must** be removed prior to cleaning.
- The stopcocks on the hysteroscope and sheath **must** be disassembled prior to cleaning and sterilization. Holding onto the stopcock handle, remove the corresponding nut, then pull the handle from the body (Figure 1).
- Scrub all crevices using a cleaning brush to remove any visible debris from all crevices, taking care to not scratch any optical surface.
- Operative channels should be cleaned with an appropriate cleaning brush.
- Thoroughly rinse the scope and any stopcocks or operative channels to completely remove the cleaning solution.

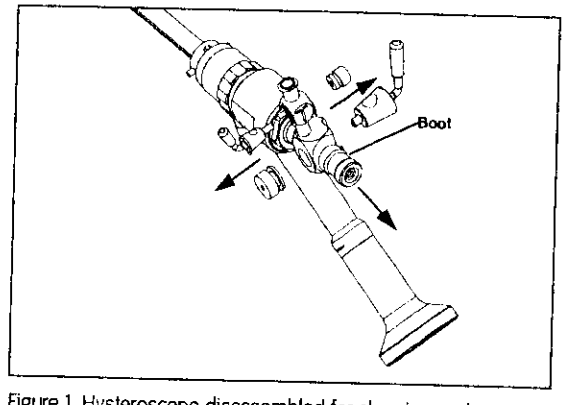


Figure 1. Hysteroscope disassembled for cleaning and sterilization

- Hysteroscopes should be soaked in an enzymatic, neutral pH cleaner for five minutes.

The scope has three optical surfaces that must be thoroughly cleaned and checked routinely to ensure both maximum transmission of illumination and a high-quality image. These are:

The distal tip

The proximal window or eyepiece

The fiber optic light post

199

Removing Deposits from Autoclavable Scope Optical Surfaces

Aluminum oxide powder (REF 7205548) is provided as an accessory to the Smith & Nephew scopes and is intended to be used, when required, to remove deposits on optical surfaces thus maintaining optical integrity and allowing the scopes to perform per their intended uses.

Note: Cleaning with aluminum oxide powder should only be performed when the image viewed through the scope is cloudy and not as part of your routine cleaning procedures.

To remove deposits, moisten a cotton-tipped swab with water. Dip the moistened swab into the aluminum oxide powder. Position the swab tip against the optical surface of the scope to be cleaned. While applying gentle pressure to the swab, scrub the window to remove any deposits. For smaller windows, rotate the swab instead of scrubbing. Rinse the optical surface with tap water and brush with a soft bristle brush while under running water to remove the aluminum oxide powder.

Note: Do not use any ultrasonic cleaning methods. The energy transmitted through fluid cavitation will damage seals and optical surfaces and will void the warranty.

Note: Foreign matter remaining on the fiber surface of the light post after cleaning may tend to burn and discolor the surface when exposed to a high intensity light source.

Sterilization

Smith & Nephew Operative Hysteroscopes should be sterilized in a container which secures the instrument in place. Be sure the outer tube does not experience any undue force or stress which can destroy the delicate internal optics. Sterilize the hysteroscope using validated methods.

CAUTION: *Not all hysteroscopes can be autoclaved. Those that can are clearly marked as autoclavable on their proximal end. Autoclaving scopes for which this was not intended may result in irreparable damage.*

Before cleaning and before sterilization the following must be performed:

Light adaptors **must** be removed

Rubber boot **must** be removed

Sheath **must** be removed

Stopcocks on the hysteroscope and sheath **must** be disassembled

Autoclaving Process Parameters

Autoclave Wrapped

Follow standard hospital procedures for:

Pre-vacuum methods at 270–275° F (132–135° C) for 4 minutes; or

Gravity methods at 270–275° F (132–135° C) for 10 minutes.

Note: These parameters have been validated by Smith & Nephew to ensure sterility. Sterilizer functioning should be monitored at regular intervals with biological indicators to ensure products have been subjected to sterilization conditions.

Assembly/Disassembly Instructions

Smith & Nephew Operative Hysteroscopes are compatible with the entire Smith & Nephew light source product line, including Metal-Halide and Xenon light sources of up to 300 watts of power. The scopes are also compatible with third party endoscopic light sources of up to 300 watts of power.

Smith & Nephew offers adaptors for the scope light post and light cable for connection to Storz, Olympus, Dyonics®/Wolf and ACMI light sources (Figure 2).

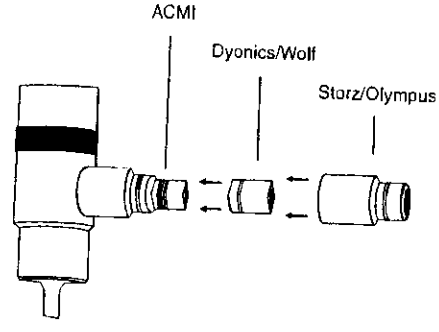


Figure 2. Adaptors for the Scope Light Post

Assembling Scopes

Place the correct adaptor(s) on the fiber optic light post of the scope and on the instrument end of the light guide. The light post threads may be lubricated as needed, being sure to remove any excess lubricant as required. Make sure that the fiber optic surface remains free of foreign matter.

Adaptors can be used to fit most light guides. Simply screw the appropriate adaptor on or off the fiber optic light post to prepare scope for connection to light guides. Do not use tools, only hand-tighten adaptors.

Assemble stopcocks and check for proper functioning.

CAUTION: *Any mechanical manipulation of the eyepiece may result in seal breakage, therefore do not attempt to remove the eyepiece.*

Hysteroscope Set Instructions

The Smith & Nephew Hysteroscope Set consists of an obturator, sheath, and hysteroscope. Refer to the Smith & Nephew Hysteroscopic Fluid Management System Operations/Service Manual (REF 1061372) for proper tubing connection to the hysteroscope and sheath.

To place obturator into sheath:

Rotate the sheath handle counterclockwise until the inner and outer slots are aligned (Figure 3). Insert the obturator into the sheath, placing the male posts of the obturator into the slots. Turn the sheath handle clockwise to lock the obturator in place. Reverse this process to remove the obturator.

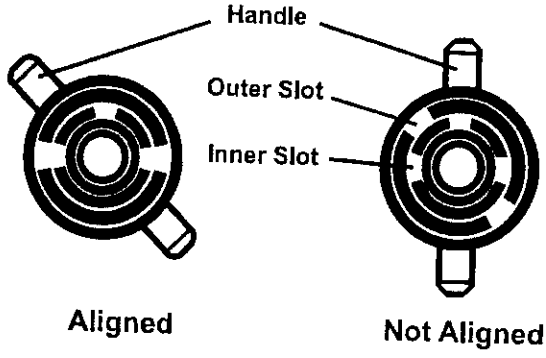


Figure 3

To place hysteroscope into sheath:

Refer to the Smith & Nephew Hysteroscopic Fluid Management System Operations/Service Manual (REF 1061372) for proper tubing connection to the hysteroscope. Rotate the sheath handle until the inner and outer slots are aligned (Figure 3). Insert the hysteroscope into the sheath, placing the male posts of the hysteroscope into the slots. Turn the sheath handle clockwise to lock the scope in place. Reverse this process to remove the hysteroscope.

Storage

1. Smith & Nephew Operative Hysteroscopes should be stored with the plastic cover on the distal working end and the eyecup. This will preserve optics by protecting the delicate needle portion and proximal window.
2. The hysteroscope and accessories should be stored either in their shipping box or in a sterilization tray. In either case, proper care should be taken to ensure that the hysteroscope is immobile to prevent any damage.

Note: Any mechanical manipulation of the eyepiece may result in seal breakage; therefore, do not attempt to remove the eyepiece.

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 4A

STANDARDS DATA FORM

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]
IEC 60601-2-18:MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ENDOSCOPIC EQUIPMENT: 1996 + AMD. 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

K105203

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

60601-2-18:MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ENDOSCOPIC QUIPMENT: 1996 + AMD. 1:2000

CONFORMANCE WITH STANDARD SECTIONS*

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		

CTION 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.

K060052
204

ATTACHMENT 4B

PERFORMANCE TEST RESULTS

Memo

To: File

From: Ron Adams

CC: David Jacobs, Bill Gruber, Albert Chin, R&D Team

Date: 4/11/2008

Re: Scope Optical Resolution Testing

Captured below is a summary of the results from scope optics testing conducted with (b)(4) Trade S t P.

Test Objective:

Document the optical characteristics of the fiber scopes.

Test Configuration:

(b)(4) Trade Secret Process - Testing

Test Equipment:

(b)(4) Trade Secret Process - Testing

Test Results:

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

Memo

To: File

From: Ron Adams

CC: David Jacobs, Bill Gruber, Albert Chin, R&D Team

Date: 4/11/2008

Re: IEC 60601-2-18 Section 42 Excessive Temperatures Testing

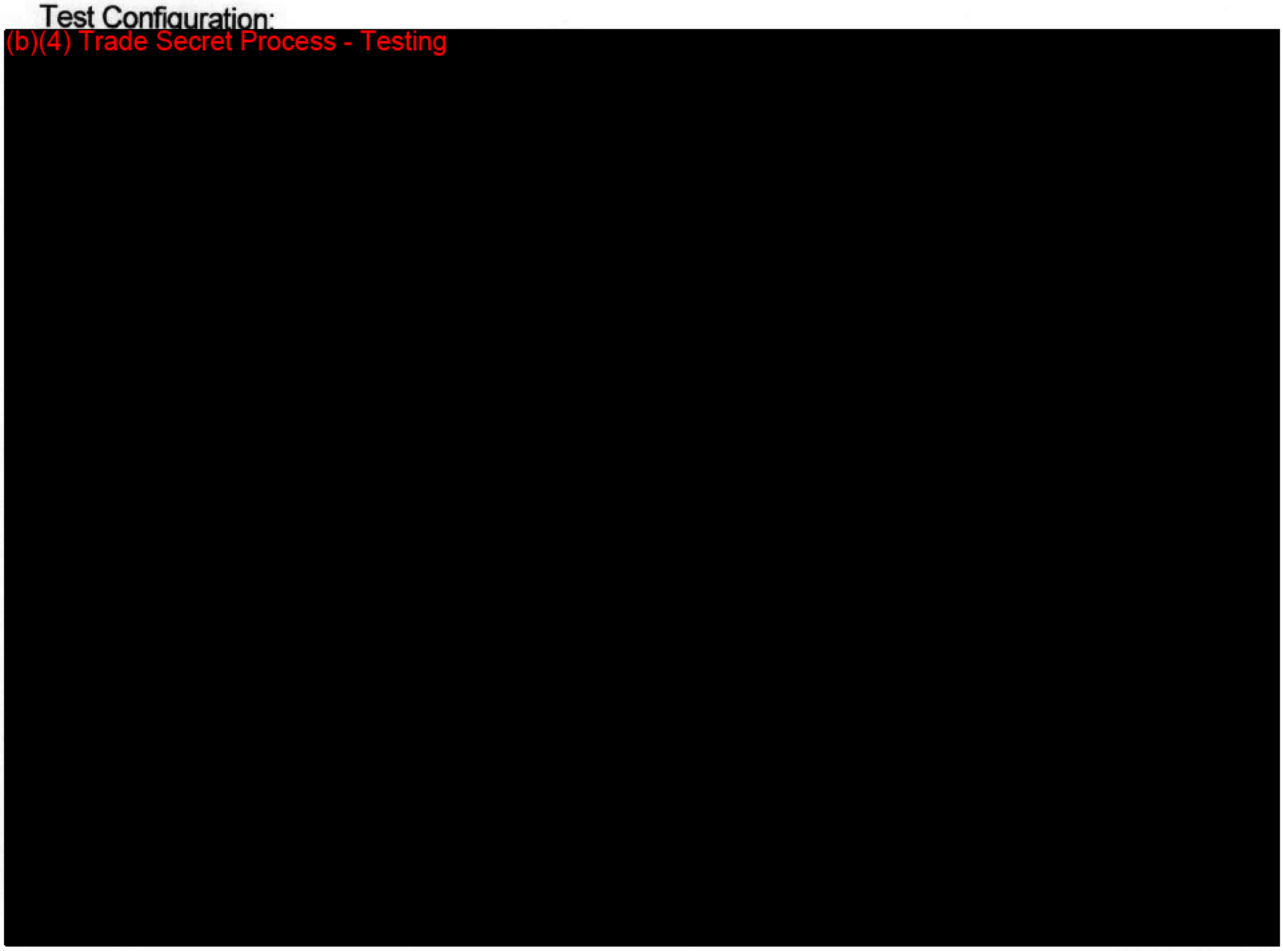
Captured below is a summary of the results from thermal testing conducted with four fiber scopes.

Test Objective:

Determine the operating surface temperatures.

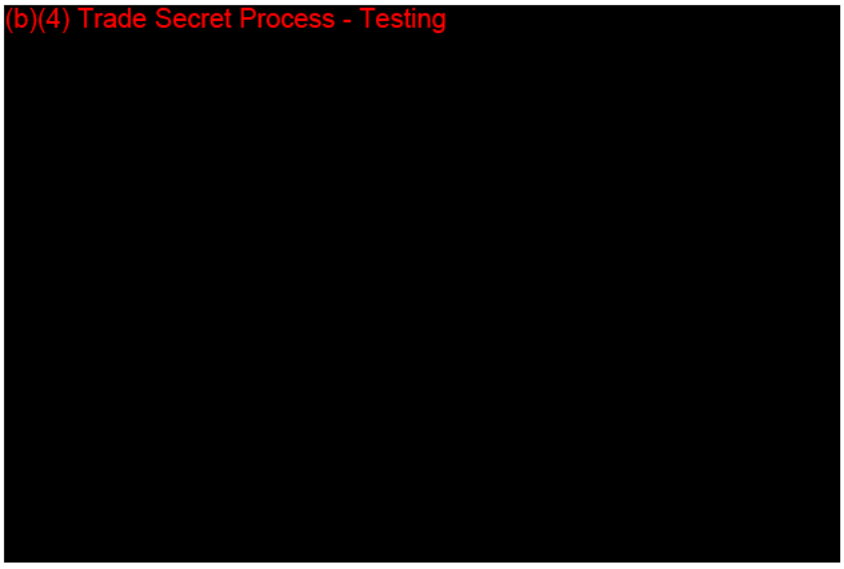
Test Configuration:

(b)(4) Trade Secret Process - Testing



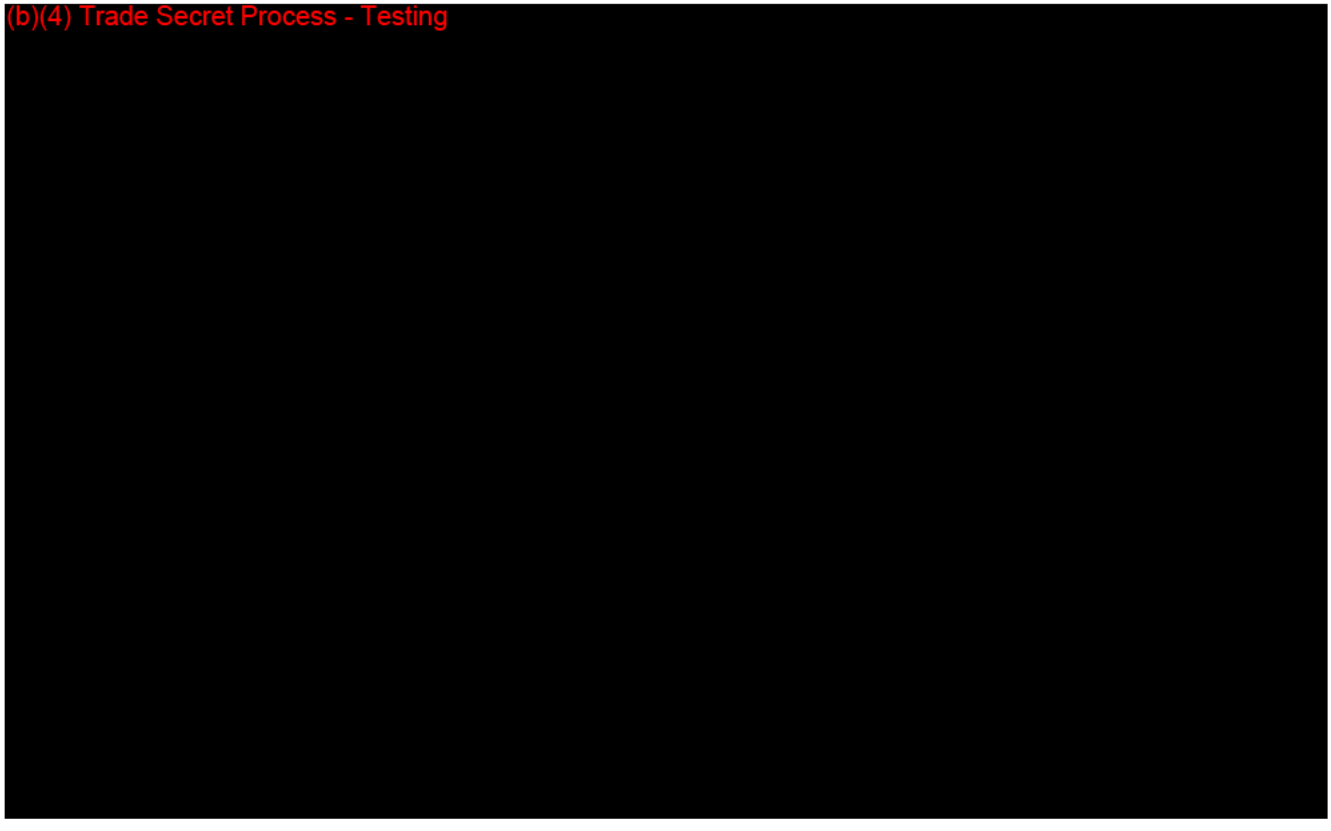
Test Equipment:

(b)(4) Trade Secret Process - Testing



Test Results:

(b)(4) Trade Secret Process - Testing



(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

ATTACHMENT 5

510K SUMMARY OF SAFETY AND EFFECTIVENESS

Interlace Medical, Inc.
Operative Hysteroscopy System
510K Summary of Safety and Effectiveness
April 11, 2008

1. Sponsor Name

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

2. Device Name

Proprietary Name: Interlace Medical Operative Hysteroscopy System
Common/Usual Name: Hysteroscope and accessories

3. Identification of Predicate or Legally Marketed Device

The Interlace Medical Operative Hysteroscopy System is substantially equivalent to the Smith and Nephew Hysteroscope and Accessories cleared under K013870

4. Device Description

The Interlace Medical Operative Hysteroscopy System is intended for use in visualizing the uterine cavity and performing operative hysteroscopy procedures. The Operative Hysteroscopy System includes an obturator, a sheath and a hysteroscope. The obturator is used to facilitate introduction of the sheath into the uterine cavity. The single use sheath includes a working channel to permit the introduction of instrumentation. The reusable fiber optic hysteroscope is designed with optical lenses for visualization and optical fibers for illumination. The obturator is inserted into the working channel of the sheath and the hysteroscope is inserted into a designated lumen of the sheath. The Operative Hysteroscopy System can be combined with a hysteroscopic fluid management system (not the subject of this submission) to provide continuous flow hysteroscopy capability. The hysteroscope can be used with standard O.R. camera couplers.

5. Intended Use

Interlace Medical Operative Hysteroscopy System is used to provide viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

6. Comparison of Technological Characteristics

The Interlace Medical Operative Hysteroscopy 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 Medical Operative Hysteroscopy System has the same intended use and

technological characteristics as the predicate device, the Interlace Medical Operative Hysteroscopy System does not raise any new safety and efficacy concerns when compared to the similar legally marketed device.

The descriptive characteristics demonstrate that the Interlace Medical Operative Hysteroscopy System are substantially equivalent to the predicate device and is capable of safely and accurately performing the stated intended use.

7 Performance Testing
The Interlace Medical Operative Hysteroscopy System meets electrical safety standards.

8. Statement of Equivalency
The Interlace Medical Operative Hysteroscopy 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 Operative Hysteroscopy System has the same in intended use and technological characteristics as the predicate device, the Interlace Operative Hysteroscopy System does not raise any new safety and efficacy concerns when compared to the similar legally marketed device.

The descriptive characteristics demonstrate that the Interlace Operative Hysteroscopy System 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 Glenn Bell

Subject: 510(k) Number K081079/S1

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/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%202%2007.doc)

☐ 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://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/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)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		✓	
Nanotechnology			✓

		yes	no
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: none

Review: Michael T. Bailey for Colin Halliwell (Branch Chief) 85 (Branch Code) 7/23/08 (Date)

Final Review: (Division Director) 7/23/08 (Date)

DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

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

Premarket Notification [510(k)] Review
Traditional

K081070

Date: July 17, 2008
To: The Record
From: Glenn Bell
Biomedical Engineer, OGDB
Office: ODE
Division: DRARD
510(k) Holder: Interlace Medical Inc.
Device Name: Interlace Medical Operative Hysteroscopy System
Contact: Ron Adams
Phone: (508) 875-1343 x102
Fax: (508) 370-8026
Email: Ron@InterlaceMedical.com
Predicates: Smith & Nephew Operative Hysteroscope and Accessories (K013870)
Karl Storz Flexible Hysteroscope (K961605)
Galileo Flexible Hysteroscope (K974297& K981928)
OmniSonics Medical Technology Endoscope (K991377)

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the Interlace Medical Operative Hysteroscopy 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	√		

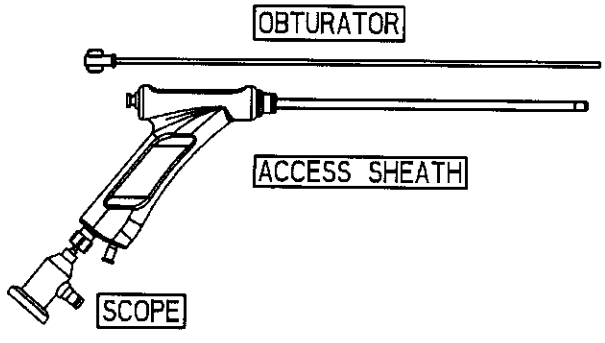
6

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?		√	
Is the device sterile?	√*		
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	√**		

*The device is not supplied sterile. It is sterilized by the user before use. The sheath and obturator are supplied sterile.
**The sheath and obturator are single use devices and the hysteroscope is reusable.

The Interlace Medical Operative Hysteroscopy System is intended for use in visualizing the uterine cavity and performing operative hysteroscopy procedures. The Operative Hysteroscopy System includes an obturator, a sheath and a hysteroscope. The obturator is used to facilitate introduction of the sheath into the uterine cavity. The single use sheath includes a working channel to permit the introduction of instrumentation. The reusable fiber optic hysteroscope is designed with optical lenses for visualization and optical fibers for illumination. The obturator is inserted into the working channel of the sheath and the hysteroscope is inserted into a designated lumen of the sheath. The Operative Hysteroscopy System can be combined with a hysteroscopic fluid management system to provide continuous flow hysteroscopy capability. The hysteroscope can be used with standard camera couplers.



The Interlace Medical Operative Hysteroscopy System is a flexible fiberoptic scope which functions by light being transmitted from a standard external high intensity light source through illumination fibers to the distal tip of the scope. The image is transmitted via an imaging bundle to an eyepiece. The image is viewed directly or transmitted through a video camera to a monitor. The Interlace Medical Hysteroscope is used with standard off the shelf light sources (Xenon or Metal Halide, up to 300 Watts).

(b)(4) Trade Secret Process - Product specs & Testing

Characteristic	Interlace Medical Operative Hysteroscopy System
(b)(4) Trade Secret Process - Product specs & Testing	

The device description was incomplete. The following parameters were not provided: fiberoptic imaging system description (# fibers, fibers per sq. mm, size of fiber core, area of active fiber per mm^2), distortion, and percent of luminous energy transmitted. It was unclear whether hysteroscope has a tip articulation feature. It was unclear whether the field of view provided is for use in air or water. The requested information was provided, although distortion was displayed pictorially instead of quantitatively. This is resolved.

IV. Indications for Use

Subject Device
Interlace Medical Operative Hysteroscopy System is used to provide viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

Predicate Device
Smith & Nephew Operative Hysteroscope (K013870, Procode HIH)
The Smith & Nephew Operative Hysteroscope and accessories are used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.

Discussion of whether the intended use/indications are the same
The indications for use of the Interlace Operative Hysteroscopy System and the Smith & Nephew Hysteroscope are the same.

V. Predicate Device Comparison

Comparison of the Technological Characteristics (Design, Materials, Sizes, Features, Shapes, etc.) of the Subject Device and Predicate

The sponsor originally did not provide a predicate device that used fiberoptic technology comparable to the Interlace Medical Hysteroscope (originally they only compared their device to the Smith and Nephew Hysteroscope K013870). The sponsor subsequently provided the following table. The underlined items were either corrected or inserted from documents from FDA's Image Database.

Substantial Equivalency Table

Characteristic	Interlace Medical Operative Hysteroscopy System	S&N Hysteroscope K013870	Storz Flexible Hysteroscope K961605	Galileo Flexible Hysteroscope K974297, K981928	OmniSonics Endoscope K991377
Dimensions	(b)(4) Trade Secret Process - Product specs & Testing				
Working Length		191 mm	240 mm	150-300 mm	≤ 150 cm
Outer Diameter		Scope – 8.5 mm Sheath – 9 mm	3.2 mm	1.3-5 mm	1.0-2.5 mm
Working channel diameter		5.5 mm x 5.4 mm	1.3 mm	1.7 mm	Not specified
Illumination					
Recommended light source		Metal halide or Xenon	Quartz halogen	Not specified - "std. external high intensity light source"	Not specified -"std. external high intensity light source"
Power rating of light source		150-300W	150 W		
Optics					

Technology	(b)(4) Trade Secret Process - Product specs & Testing	rod lens	fiber optic	fiber optic	Fiber optic
Depth of Field		3mm - ∞	2 – 50 mm	5 – 40 mm	5-40 mm
Direction of view		0°	0°	0-30°	0
Field of view in Air/Water		Air 80°+10°-5°	Air 85°	40-70°	70
Resolution		7.1 line pairs/mm	3 line pairs/mm	USAF Grp 2 Element 5 or better	USAF Grp 2 element 5 or greater
Magnification		21x	35x	6.7X-30X	7X
Focus Distance		1.3 mm	Est. 15 mm	Unknown	Not specified
Distortion		Photo provided, 20%	Photo provided	Unknown	Not specified
# Image fibers		N/A	7957	10k	Not specified
Image Fibers per sq. mm		N/A	13862	Unknown	Not specified
Size of fiber core		N/A	6.9 microns	Unknown	Not specified
Area of active image fiber per mm^2		N/A	0.65	Unknown	Not specified
Pixel Count		N/A	Unknown	10K-50K	10,000-50,000
Thermal Specs.					
Max. Temp.		23.8°C	<35°C	Unknown	Not specified
Luminous energy transmit		12%	0.8%	Unknown	Not specified
Mechanics					
Tip Articulation		No	Yes	No	Not specified
Reusable or disposable		Reusable	Reusable	Disposable	reusable
How introduced		Transcervical-access sheath/obturator	Transcervical – direct, no access sheath req'd	Transcervical – directly or with sheath	Natural body cavities or surgical incision through introducer, needle, catheter, etc.
RF Electrosurgical Features		None – intended for use w/ mechanical morcellator	None - Working channel can accept bx forceps	None - Working channel can accept 1.7 mm devices	Not specified

The information provided indicates that the Interlace Medical Hysteroscope has the same technological characteristics as the predicate devices (including photographs of the distortion). This is resolved.

Sheath:
The sheath includes an open channel capable of accepting the Interlace Medical hysteroscope, 2 irrigation channels, and a 3 mm instrument channel for the introduction of the Interlace morcellator. The sheath has a 25 cm working length and is 5.0 to 6.0 mm in outer diameter. The sheath is compatible with 2 mm and smaller hysteroscopes and also is compatible with diagnostic and therapeutic devices < 3.0 mm.

Obturator:
(b)(4) Trade Secret Process - Product specs & Testing

[redacted]

VI. Labeling

The sponsor supplied a copy of the Operating Manual and device labels.

All of the requested labeling changes were implemented in the Operating Manual. This is resolved.

VII. Sterilization/Shelf Life/Reuse

The Interlace Medical Hysteroscope is supplied non-sterile and must be sterilized by the user prior to use.
Sterilization method: Ethylene Oxide Gas
(55°C, 35-70% relative humidity, 736 mg/l gas concentration, 60 minutes exposure time, 11 hours aeration time)
Traditional
Validation method: Use of biological indicator

Sheath and Obturator:
The sheath will be provided sterile and are sterilized using ethylene oxide gas by a contract sterilization company. 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 sheath device is 10^{-6}.

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 sheath and obturator are provided sterile for single use. The packaging in which the Sheath will be placed is on a HDPE backing in a standard Tyvek/mylar pouch. The product will be labeled with an expiration date of 6 months from the date of sterilization and subsequently validated later to 2 years. Interlace will have validated the packaging and sterilization processes prior to marketing.

Cleaning
- Scrub using a cleaning brush (avoid optical surface)
- Soak in enzymatic cleaner (5 minutes, pH neutral)
- Rinse
- Check optical surfaces – distal tip, proximal window, fiber optic light post
- Use aluminum oxide powder to remove any deposits from optical surfaces (using cotton swab with water)

Alison Cotterell provided a review of the sterilization and cleaning.

In Alison's prior review she requested the sponsor provide:

- Validation for the cleaning process
- A more complete description of the validation for the sterilization process
- Name and address of the contract sterilizer
- Labeling for of each part of the device indicating whether it is reusable or single-use only
- Absolute values of the residuals after sterilization
- Description of testing used to ensure 6-month shelf life

(b)(4) Trade Secret Process - Product specs & Testing

[redacted]

VIII. Biocompatibility

In response to a request for more detailed biocompatibility information regarding the location of the materials and type of contact the sponsor provided the following (with my edits based on information found in Image):

(b)(4) Trade Secret Process - Product specs & Testing

The sponsor also supplied diagrams of the device components with the locations of the various materials. The sponsor has shown that the same materials are used in 510(k) cleared devices with similar contact. Many of the materials have minimal contact, are benign materials, or are commonly used materials. This is resolved.

IX. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Electrical Safety/ EMC Testing

The sponsor states that the device is in compliance with IEC/EN 60601-2-18:1996 - Medical electrical equipment -- Part 2: Particular requirements for the safety of endoscopic equipment. A Standards Data Report form was provided, but a copy of the test results was not provided.

Enclosure and patient leakage currents are not needed since there are no electrical components or power sources in the device. EMC testing is not required since there are no electrical components or power sources in the device. This is resolved.

Thermal Safety

Thermal Safety Testing per IEC 60601-2-18

(b)(4) Trade Secret Process - Product specs & Testing

[redacted]

X. Performance Testing – Bench

Optical Resolution Test

Optical results were provided using two fiber scopes. Digital images of a test target were captured using a digital camera. The sponsor indicates that the image resolution is adequate for diagnostic and therapeutic hysteroscopy.

The sponsor was asked to describe validation testing conducted on the product. The sponsor indicated that hysteroscope will undergo an inspection for dimensional/mechanical, optical, illumination, and labeling (an endoscope QC form was provided, which shows the characteristics that are tested). The sponsor also indicated that the sheath will undergo pressure tests on both the inflow and outflow lumens to insure that no leakage is observed. This is resolved.

The submission indicates that the device will be used for both diagnostic and operative hysteroscopy. This means that the device must be used with an irrigation sleeve, laser equipment, and other ancillary instrumentation. The sponsor was asked to provide specific descriptions of the ancillary equipment to be used with their hysteroscope for operative procedures. The sponsor has indicated that the sheath includes a (b)(4) Trade Secret [redacted] *designed to accommodate the Interlace Medical Morcellator (K073690). The sheath includes integral irrigation lumens to facilitate its use for continuous flow hysteroscopy. The sheath is not designed to accommodate other ancillary equipment. This is resolved.*

XI. 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**

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

5. The descriptive characteristics are not precise enough.

8. The following performance data are needed: more detailed device characterization/description, biocompatibility data, leakage current test results, EMC testing and results, validation tests and results, listing of ancillary equipment for operative procedures and compatibility testing.

9. The data provided demonstrates substantial equivalence of the Interlace Medical Operative Hysteroscopy System with the predicate devices. All deficiencies have been adequately addressed.

XII. Contact History

7/17/08 Email from Ron Adams indicating that they plan to conduct the cleaning validation without measurement of protein levels or total organic carbon levels
7/15/08 Teleconference with Ron Adams and Don Tumminelli (contract test company rep.) regarding additional endpoint for the cleaning validation protocol (protein and total organic carbon)
7/10/08 Called Ron Adams and emailed him recommended additional endpoints for the cleaning validation protocol
6/18/08 received revised electronic copy of submission
6/13/08 received electronic copy of submission

XIII. Recommendation

I recommend that the Interlace Medical Operative Hysteroscopy System be considered substantially equivalent to the predicate hysteroscopes.

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

G. Bell
Reviewer

7/17/08 VAP 7/15/08
Date

Colin Pollard
Branch Chief

7/22/08
Date

Draft: GBB 7/10/08
Revised: GBB 7/11/08 (VAP input)
Revised: GBB 7/17/08

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

Date: July 9, 2008

From: Alison A. Cotterell, Ph.D.,
Microbiologist,
DRARD, OGDB

Subject: **K081070** – Interlace Medical Operative Hysteroscopy System
Sterility Consult Review

To: Glenn B. Bell, Ph.D.
Biomedical Engineer
DRARD, OGDB

Applicant: Interlace Medical Inc.
139 Newbury St
Framingham, MA 01701

Contact: Ron Adams
Chief Technical Officer

SCOPE OF REVIEW

This consult is limited to a review of responses to deficiencies 4-9 of the May 15, 2008 "Request for Additional Information (AI)" letter.

REASON FOR SUBMISSION

The purpose of this 510(k) is to introduce the Interlace Medical Operative Hysteroscopy System into interstate commerce.

DEVICE DESCRIPTION

The Interlace Medical Operative Hysteroscopy System is for use in visualizing the uterine cavity and performing operative hysteroscopy procedures. The Operative Hysteroscopy System includes an obturator, a sheath and a hysteroscope. The obturator is used to facilitate introduction of the sheath into the uterine cavity. The single-use sheath includes a working channel to permit the introduction of instrumentation. The reusable fiber optic hysteroscope is designed with optical lenses for visualization and optical fibers for illumination. The obturator is

inserted into the working channel of the sheath and the hysteroscope is inserted into a designated lumen of the sheath. The Operative Hysteroscopy System can be combined with a hysteroscopic, fluid management system to provide continuous flow hysteroscopy capability. The hysteroscope can be used with standard camera couplers.

The Interlace Medical Operative Hysteroscopy System is a flexible fiberoptic scope, which functions by light being transmitted from a standard external high intensity light source through illumination fibers to the distal tip of the scope. The image is transmitted via an imaging bundle to an eyepiece. The image is viewed directly or transmitted through a video camera to a monitor. The Interlace Medical Hysteroscope is used with standard off the shelf light sources (Xenon or Metal Halide, up to 300 Watts).

INDICATIONS FOR USE
The Interlace Medical Operative Hysteroscopy System is used to provide viewing of the cervical canal and the uterine cavity in order to perform diagnostic and surgical procedures.

REVIEW OF RESPONSES TO AI LETTER
In the previous review round, I recommended that the following deficiency questions (in bold font) be sent to the sponsor. The sponsor provided the following responses (in normal font below each question):

4. **According to the guidance document, "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance (1996)", it is the responsibility of the OEM to provide the user with cleaning and sterilization procedure that has been successfully validated. On page 3 of your operating manual, you briefly describe the cleaning process to be used on your device; however, you have not described how you validated this process. For devices that are reusable between multiple patients, cleaning validation studies should be conducted using organic soil containing hemoglobin, protein and/or carbohydrate. Therefore, please validate your cleaning method and provide a detailed description of the method used and results observed. Please note that your results should indicate the levels of hemoglobin, protein and/or TOC on your device before and after cleaning.***

The sponsor states that they have contracted with an FDA Registered firm (b) (4) [redacted] to conduct these tests on a series of hysteroscopes. They include copies of the cleaning validation protocol, along with standards forms FDA 3654 for ISO 17644, AAMI TIR-12 and TIR-30 Procedures for the Cleaning and Use of Reusable Medical Devices. Interlace Medical Inc. indicates that this testing will be completed prior to marketing the Interlace Medical device.

The protocol details the methods that will be used to sterilize the Interlace™ Medical Hysteroscopes. It states that three (3) hysteroscopes will be inoculated with an artificial soil containing 1.0×10^4 *Geobacillus stearothermophilus* spores in "hardest-to-clean" areas of the device. The devices will then be allowed to dry and then be cleaned using the manufacturer's

protocol. This method will be considered successfully validated if there is a ≥ 3 log reduction in the number of spores recovered.

If a device is to be reused on multiple patients, cleaning validation studies should be conducted using organic soil containing protein and carbohydrate, at minimum. According to TIR 30, bacteria and spores used for assessment of the bioburden reduction because of cleaning are *not* a substitute for soil markers for cleaning efficacy, since it is possible that the cleaning reagents kill the test organisms but the organic debris, viz., protein and carbohydrate, from these dead microbes may still remain adhered to the device. These organic residues are often resistant to sterilization. Furthermore, from a clinical perspective, residual protein remaining on a device after sterilization is able to elicit immunogenic responses in some individuals. In addition, carbohydrate residuals can indicate the presence of a biofilm on the device: Biofilms are highly resistant to most sterilization processes. Therefore, measuring protein and total organic carbon (TOC) before and after cleaning is a more accurate method of determining wether a device is *clean*.

Although such cleaning validation procedures are not required by FDA, we cannot *force* them to do such thorough testing; however I recommend that the sponsor provide at least protein and TOC residual information before and after cleaning their device using their cleaning procedure.

5. **Similarly, you have not fully described how you validated your sterilization method, (citing the standard used is not adequate). Therefore, please provide a detailed description on your sterilization validation process. This description should include a load configuration diagram showing where the devices are placed in the ehtylene oxide (EtO) chamber and "worst-case" placement of at least 10 biological indicators on each device). In addition, please provide us with all your raw data results. (Note that you should use at least three of your devices, or appropriate Process Challenge Devices, in your validation process.)***
   (Your Contract Sterilizer should be able to provide you with this information).

The sponsor states that they have contracted with an FDA Registered firm (b) (4) [redacted] to conduct these tests on a series of hysteroscopes. They include copies of the Ethylene Oxide Sterilization validation protocol, along with standards forms FDA 3654 for ISO 11135 Sterilization of Health Care Products, Ethylene Oxide: Requirements for development, validation, and routine control of a sterilization process for medical devices:2007. They indicate that they have contracted with FDA Registered firms (b) (4) [redacted] to conduct these tests on the sheath and (b) (4) [redacted] hysteroscope. Interlace Medical Inc. adds that this testing will be completed prior to marketing the Interlace Medical device.

(b) (4) [redacted]

(b) (4)

[redacted]

The overkill method was selected to verify the sterilization efficacy of the Interlace™ Medical Hysteroscopes per AAMI guidelines. In this method, validation is accomplished by demonstrating that a minimum of 1.0×10^6 highly resistant *Bacillus atrophaeus* spores will be killed in a half-cycle. A full cycle would therefore result in a 12-log reduction of spores and produce a 10^{-6} sterility assurance level (SAL).

This response is acceptable.

6. **Please provide the name and address of your Contract Sterilizer.**

Interlace Medical Inc. provides the following name and address of their contract sterilizer:

(b) (4)

[redacted]

This issue is resolved.

7. **Please clearly and appropriately label each of the parts of your device as reusable (non-sterile, to be cleaned and sterilized prior to each use) or single-use only (sterile, discard after single-use).**

Interlace Medical Inc. states that both Box and Package labels on sheath incorporate the single-use graphic indicating that only one use is intended. They agree to add a label to the body of the hysteroscope indicating that it must be sterilized before use in a manner similar to the predicate device (K013870). They have enclosed copies of the labels and a drawing of the scope.

This response is acceptable.

8. **You indicate that the sterilization residuals levels after sterilization are as follows EtO = < 20mg/day, Ethylene Chlorohydrin (EC) = < 12 mg/day. Please provide the exact values of these residuals.**

The sponsor points out that the actual results EtO and EC residual results will not be available until the sterilization validation is completed, but that the results *will* be below the limits for

devices of limited exposure as specified prior to marketing the device. They include the procedure for EtO residual testing in this submission.

This response is acceptable.

6. **You describe your device packaging as having a HDPE backing in a standard Tyvek/Mylar pouch. In addition, you indicate that, "the product will be labeled with an expiration date of 6 months from the date of sterilization and subsequently validated later to 2 years". However, you have not described the testing conducted to ensure that the sheath maintains its sterility for 6 months in "worst-case" storage conditions. Therefore, please provide descriptions of your package integrity and shelf life testing protocols used to provide this assurance.**

The sponsor encloses copies of the test protocols for Pouch Seal Validation and Shelf Life (Accelerated Aging) in this submission. In addition, they indicate that they intend to drop the target shelf life from 2 years to 1 year for the initial production products as outlined in the shelf life protocol.

Pouch Seal Packaging Validation protocol is aimed to substantiate and document that the pouch/seal packaging provides effective and consistent seals, which will maintain the intended sterile barrier for the product. The protocol is designed to comply with ISO 11607, Packaging for Terminally Sterilized Medical Devices. Tensile testing will be conducted in accordance with ASTM F88-99, Standard Test Method for Seal Strength of Flexible Barrier Materials.

This validation encompasses the operational qualification (process challenge) and the performance qualification (nominal operating parameters). In addition, it qualifies the sealing process for the pouch seal at the operating parameters. Samples will be tested both before the sterilization cycle and after the sterilization cycle. This will ensure sterilization does not adversely affect seal strength integrity. The pouch sealing process will be assessed by seal integrity, width, tensile testing, and dye penetration or burst testing.

The Shelf Life testing protocol defines the test methods and acceptance criteria, required to perform accelerated age testing on the Sheath. Testing defined in this protocol includes visual examination, dimensional inspection, and functional testing after environmental exposures equivalent to 0 (base line), 6 and 12 months of shelf life.

This response is acceptable.

CONCLUSION

I recommend that the sponsor provide at least protein and TOC residual information before and after cleaning their device using their cleaning procedure, in order to validate their cleaning procedure. However, I will let the lead reviewer decide whether he wants to press this issue.

Reviewer: Alison A. Cotterell, Ph.D. 7/10/08 Date

Bell, Glenn

From: Ron Adams [Ron@InterlaceMedical.com]
Sent: Thursday, July 17, 2008 12:41 PM
To: Bell, Glenn
Subject: Proceed as filed

Yesterday, we contacted a third party, (b) (4) and they confirmed that they can do the protein test. We are still waiting for their quote for the cost of the testing but they have already identified that it will require 6 additional units and take 4-6 weeks to complete the testing. In addition, when queried about the potential for failing the protein test, they responded that presently there is no general consensus on an acceptance criteria for the test. Therefore, they do not provide a pass/fail indication only a statement of results.

Since we would need to complete the build of the test units and the testing before starting our clinical evaluations, we would prefer to stick to the submitted validation protocol.

We appreciate your quick response and willingness to discuss the matter.

Regards,

Ron Adams
Chief Technolgy Officer
Interlace Medical
139 Newbury Street
Framingham, MA 01701
O 508.875.1343 ext 102
M 508.944.5166

PRIVILEGED AND CONFIDENTIAL COMMUNICATION

This electronic transmission, and any documents attached hereto, may contain confidential and/or legally privileged information. The information is intended only for use by the recipient named above. If you have received this electronic message in error, please notify the sender and delete the electronic message. Any disclosure, copying, distribution, or use of the contents of information
received in error is strictly prohibited.

==========

Bell, Glenn

From: Bell, Glenn
Sent: Thursday, July 10, 2008 4:25 PM
To: 'Ron Adams'
Cc: Cotterell, Alison
Subject: K081070 Interlace Medical

Ron,

Please let me know if you are able to make the recommended change to the cleaning validation protocol (see below). If so, then please provide me an email documenting that your testing will include the recommended change.

> In your Cleaning Validation protocol, you propose that the acceptance criteria for the device being "clean" is a 3-log reduction in G. stearothermophilus after cleaning. According to TIR 30, bacteria and spores used for assessment of the bioburden reduction because of cleaning are not a substitute for soil markers for cleaning efficacy, since it is possible that the cleaning reagents kill the test organisms but the organic debris, viz., protein and carbohydrate, from these dead microbes may still remain adhered to the device. These organic residues are often resistant to sterilization. Furthermore, from a clinical perspective, residual protein remaining on a device after sterilization is able to elicit immunogenic responses in some individuals. In addition, carbohydrate residuals can indicate the presence of a diverse biofilm on the device. Biofilms are highly resistant to most sterilization processes. Therefore, I recommend that you measure protein and total organic carbon (TOC) on the device before and after cleaning and provide a summary of the results, along with a predetermined acceptance criteria for each test.

Sincerely,

Glenn

Glenn B. Bell, Ph.D.
Biomedical Engineer
FDA/CDRH/DRARD/OGDB
9200 Corporate Blvd.
Rockville, MD 20850
(240) 276-4106
FAX (240) 276-4156

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone

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

COVER SHEET MEMORANDUM

From: Reviewer Name Glenn Bell

Subject: 510(k) Number K081070

To: The Record

Please list CTS decision code AI

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- ☐ 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://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/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)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		✓	
Nanotechnology			✓

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: none

Review: Colin M Pollard — (Branch Chief) — OGDB — (Branch Code) — 5/15/08 — (Date) — MAY 15 2008

Final Review: _____ — (Division Director) — (Date)

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

K081070

Date: May 9, 2008
To: The Record
From: Glenn Bell
Biomedical Engineer, OGDB
Office: ODE
Division: DRARD
510(k) Holder: Interlace Medical Inc.
Device Name: Interlace Medical Operative Hysteroscopy System
Contact: Ron Adams
Phone: (508) 875-1343
Fax: (508) 370-8026
Email: Ron@InterlaceMedical.com
Predicate: Smith & Nephew Operative Hysteroscope and Accessories (K013870)

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the Interlace Medical Operative Hysteroscopy 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	√		

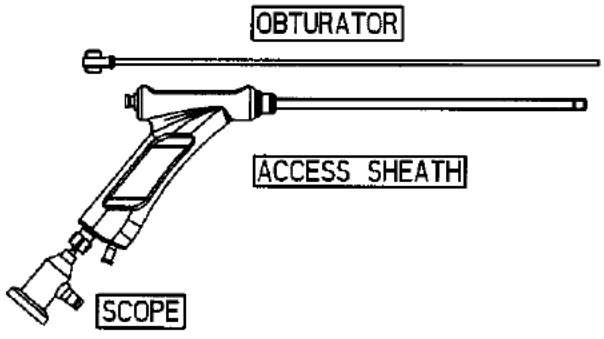
III. Device Description

	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?		√	
Is the device sterile?	√*		
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	√**		

*The device is not supplied sterile. It is sterilized by the user before use. The sheath and obturator

are supplied sterile.
**The sheath and obturator are single use devices and the hysteroscope is reusable.

The Interlace Medical Operative Hysteroscopy System is intended for use in visualizing the uterine cavity and performing operative hysteroscopy procedures. The Operative Hysteroscopy System includes an obturator, a sheath and a hysteroscope. The obturator is used to facilitate introduction of the sheath into the uterine cavity. The single use sheath includes a working channel to permit the introduction of instrumentation. The reusable fiber optic hysteroscope is designed with optical lenses for visualization and optical fibers for illumination. The obturator is inserted into the working channel of the sheath and the hysteroscope is inserted into a designated lumen of the sheath. The Operative Hysteroscopy System can be combined with a hysteroscopic fluid management system to provide continuous flow hysteroscopy capability. The hysteroscope can be used with standard camera couplers.



The Interlace Medical Operative Hysteroscopy System is a flexible fiberoptic scope which functions by light being transmitted from a standard external high intensity light source through illumination fibers to the distal tip of the scope. The image is transmitted via an imaging bundle to an eyepiece. The image is viewed directly or transmitted through a video camera to a monitor. The Interlace Medical Hysteroscope is used with standard off the shelf light sources (Xenon or Metal Halide, up to 300 Watts).

(b)(4) Trade Secret Process - Engineering Design

IV. Indications for Use

Subject Device
Interlace Medical Operative Hysteroscopy System is used to provide viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

Predicate Device
Smith & Nephew Operative Hysteroscope (K013870, Procode HIH)

The Smith & Nephew Operative Hysteroscope and accessories are used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.

Discussion of whether the intended use/indications are the same
The indications for use of the Interlace Operative Hysteroscopy System and the Smith & Nephew Hysteroscope are the same.

V. Predicate Device Comparison

Comparison of the Technological Characteristics (Design, Materials, Sizes, Features, Shapes, etc.) of the Subject Device and Predicate

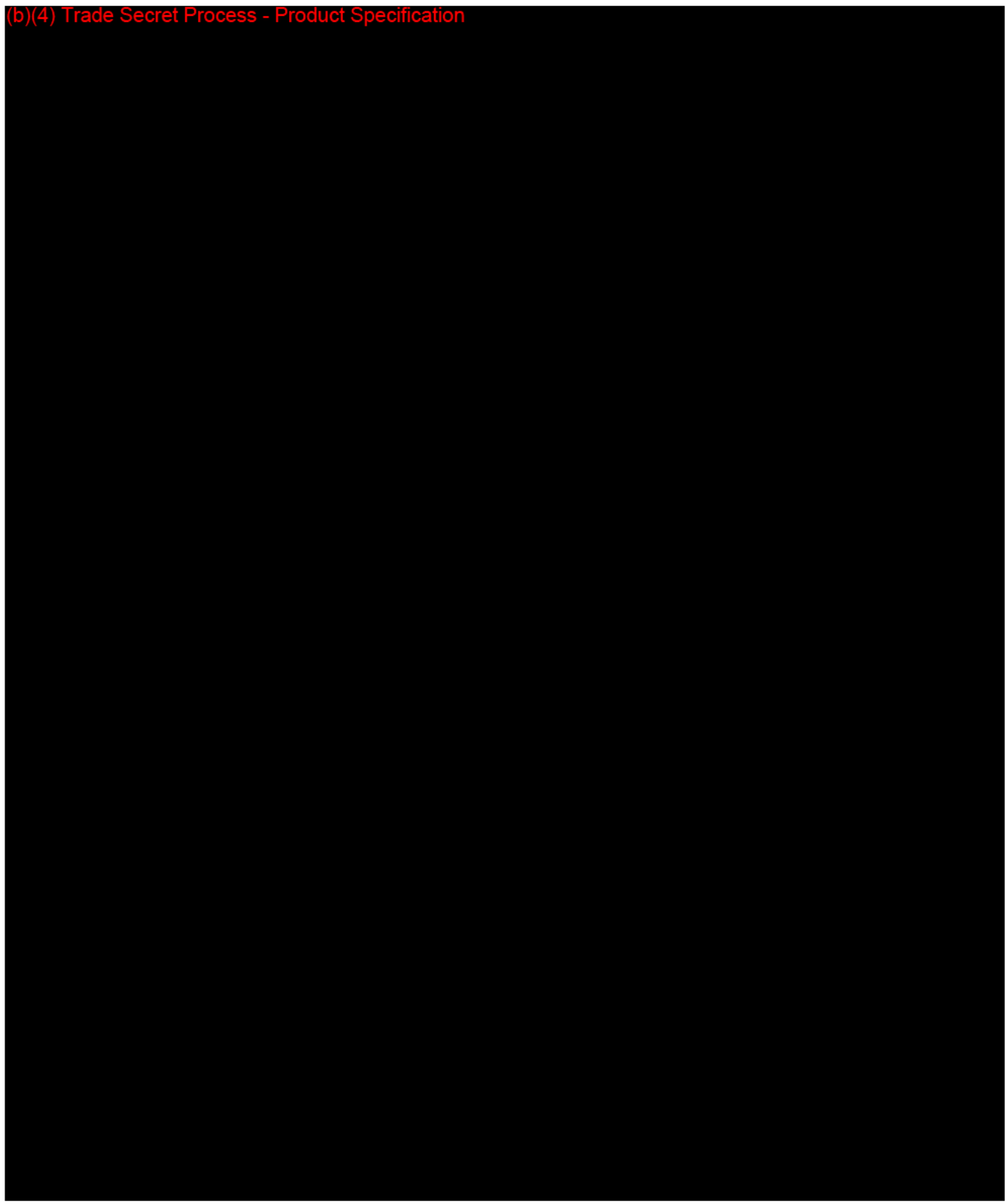
Characteristic	Interlace Medical Operative Hysteroscopy System	Smith and Nephew Hysteroscope and Accessories (K013870)
(b)(4) Trade Secret Process - Product Specification	[redacted]	

The device description is incomplete. The following parameters are not provided: fiberoptic imaging system description (# fibers, fibers per sq. mm, size of fiber core, area of active fiber per mm^2), distortion,

and percent of luminous energy transmitted. It is unclear whether hysteroscope has a tip articulation feature. It is unclear whether the field of view provided is for use in air or water.

The sponsor should provide a predicate device that uses fiberoptic technology comparable to the Interlace Medical Hysteroscope. Other hysteroscopes have been approved that use fiberoptic technology see below (These predicates were not provided by the sponsor):

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



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

[redacted]

Sheath:

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

[redacted]

Obturator:

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

[redacted]

VI. Labeling

The sponsor supplied a copy of the Operating Manual and device labels.

Operating Manual

On page 32, please add the following sentence under Indications for Use: "Note: Hysteroscopes are used as tools for access to the uterine cavity and are not, in and of themselves, a method of surgery."

On page 32, under Diagnostic Hysteroscopy, please add a bullet for" Inrauterine Foreign Body", delete "and pregnancy wastage", and add "or sonohysterogram" after "Evaluation of abnormal hysterosalpingogram."

On page 32, under Operative Hysteroscopy, please add a bullet for "Endometrial Ablation", add the word "endometrial" before biopsy, and replace "Removal of submucous fibroids and large polyps" with "Polypectomy."

On page 32 prior to "Contraindications to Hysteroscopic Myomectormy," please add the following section:

Contraindications to Endometrial Ablation

Hysteroscopic endometrial ablation, whether by laser or electrosurgery, should not be undertaken without adequate training, preceptorship, and clinical experience. Additionally, endometrial biopsy should be performed prior to any ablation. The following are clinical conditions that can significantly complicate hysteroscopic endometrial endometrial ablation:

- *Adenomatous Endometrial Hyperplasia*
- *Uterine Leiomyoma*
- *Severe Adenomyosis*
- *Pelvic Pain (Subtle PID)*

- *Uterine anomalies*

On page 33, please change the title from "For Continuous Flow Hysteroscopy" to "For Continuous Fluid Flow Hysteroscopy" and please change the following text from:

"If liquid distension medium is used, strict fluid intake and output surveillance should be maintained."

to:

"If a liquid distension medium is used, strict fluid intake and output surveillance should be maintained to ensure that fluid deficit is known at all times. Depending on whether non-electrolyte or electrolyte solution is being used, when excessive fluid deficit occurs, consideration should be given to stopping further infusion and concluding the procedure".

On page 33, please change the title from "Potential Complications of Continuous Flow Hysteroscopy" to "Potential Complications of Continuous Fluid Flow Hysteroscopy" and add the following bullets to the list of potential complications:

- *Uterine perforation resulting in possible injury to bowel, bladder, major blood vessels, and ureter*
- *Death*

Please add the following section after the section on potential complications of continuous fluid flow hysteroscopy:

For Continuous CO_2 Flow Hysteroscopy

If CO_2 gas is used as a distension medium, operative hysteroscopy is contraindicated due to the risk of gas embolization. CO_2 gas may be used for diagnostic procedures. It is extremely important that a hysteroscopic insufflator is used. Death has been reported when laparoscopic CO_2 insufflators were used during hysteroscopy. Flow of CO_2 should be limited to <100 mL/min, and intrauterine pressure should not exceed 100 mmHg.

Potential complications of Continuous flow hysteroscopy with CO_2:

- *CO_2 embolization*
- *Circulatory collapse*
- *Death*

On page 33, under Precautions, please add the following:

A thorough understanding of the principles and techniques involved in laser and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device and other medical instruments. Ensure that insulation or grounding is not compromised.

On page 33, please replace the current precaution wording regarding intrauterine fluid distension (second bullet) with the following:

Gravity fed intrauterine fluid distension can usually be accomplished with pressures in the rage of 35-75 mmHg. Hanging the fluid distention medium 42 inches above the patient can generate intrauterine pressure of approximately 80 mmHg. Unless the systemic blood pressure is excessive, it is seldom necessary to use pressures greater than 75-80 mmHg.

VII. <u>Sterilization/Shelf Life/Reuse</u>

The Interlace Medical Hysteroscope is supplied non sterile and must be sterilized by the user prior to use. Sterilization method: Ethylene Oxide Gas

(55°C, 35-70% relative humidity, 736 mg/l gas concentration, 60 minutes exposure time, 11 hours aeration time)
Traditional
Validation method: Use of biological indicator

Sheath and Obturator:
The sheath will be provided sterile and are sterilized using ethylene oxide gas by a contract sterilization company. 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 sheath device is 10^{-6}.

Maximum residue levels for release purposes of Ethylene Oxide, Ethylene Chlorohydrin, and Ethylene Glycol are maintained in accordance with 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 sheath and obturator are provided sterile for single use. The packaging in which the Sheath will be placed is on a HDPE backing in a standard Tyvek/mylar pouch. The product will be labeled with an expiration date of 6 months from the date of sterilization and subsequently validated later to 2 years. Interlace will have validated the packaging and sterilization processes prior to marketing.

Cleaning
- Scrub using a cleaning brush (avoid optical surface)
- Soak in enzymatic cleaner (5 minutes, pH neutral)
- Rinse
- Check optical surfaces – distal tip, proximal window, fiber optic light post
- Use aluminum oxide powder to remove any deposits from optical surfaces (using cotton swab with water)

Alison Cotterell provided a review of the sterilization and cleaning.

In Alison's review she states "The sponsor provides an outline for the cleaning and sterilization procedures to be use on their device; however, this information is incomplete. Therefore, the sponsor should be asked to provide in depth protocols and validation methods for their cleaning and sterilization procedures so that we can better assess the efficacy of these methods."

The sponsor will be requested to provide:

- Validation for the cleaning process
- A more complete description of the validation for the sterilization process
- Name and address of the contract sterilizer
- Labeling for of each part of the device indicating whether it is reusable or single-use only
- Absolute values of the residuals after sterilization
- Description of testing used to ensure 6-month shelf life

For further details, see Alison's review.

VIII. <u>Biocompatibility</u>

The fluid path and patient contacting components of the Interlace Operative Hysteroscopy System are identified in the following table:

Material	Prior Usage
(b)(4) Trade Secret Process - Product Specification	

The sponsor should provide more detailed descriptions of the patient contacting materials of the hysteroscope system including a drawing showing the location of the materials and the CAS #s and manufacturers of the materials. The sponsor should indicate whether the patient contacting materials are identical to those used in the predicate devices and describe any colorants used.

The sponsor should discuss whether there is possible interaction of the materials.

The sponsor should provide a description of the relative amounts of the materials in the predicate devices to that in the hysteroscope system and describe the whether the materials have similar types of patient contact.

If sufficient information is not supplied, then biocompatibility testing including system toxicity may be required.

IX. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Electrical Safety/ EMC Testing

The sponsor states that the device is in compliance with IEC/EN 60601-2-18:1996 - Medical electrical equipment -- Part 2: Particular requirements for the safety of endoscopic equipment. A Standards Data Report form was provided, but a copy of the test results was not provided.

Please provide the following leakage currents:
Enclosure leakage current:
Patient leakage current:

There was no discussion of EMC testing. The sponsor should either supply evidence of compliance with IEC 601-1-2 or justify why this information is unnecessary.

Thermal Safety

Thermal Safety Testing per IEC 60601-2-18

(b)(4) Trade Secret Process -Testing

[redacted]

X. Performance Testing – Bench

Optical Resolution Test

(b)(4) Trade Secret Process -Testing

[redacted]

A list of validation tests was not provided.

The submission indicates that the device will be used for both diagnostic and operative hysteroscopy. This means that the device must be used with an irrigation sleeve, laser equipment, and other ancillary instrumentation. Please provide specific descriptions of the ancillary equipment to be used with your hysteroscope for operative procedures. In addition, describe what steps (including testing, if any) you have taken to ensure that these instruments are compatible with your hysteroscope.

XI. 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:

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

5. The descriptive characteristics are not precise enough.

8. The following performance data are needed: more detailed device characterization/description, biocompatibility data, leakage current test results, EMC testing and results, validation tests and results, listing of ancillary equipment for operative procedures and compatibility testing.

XII. Deficiencies

Device Description

1. In section II you provided a description of the Interlace Medical Operative Hysteroscopy System. Please provide a more complete description/characterization of the device. Please provide the following parameters:
   - fiberoptic imaging system description (# fibers, fibers per sq. mm, size of fiber core, area of active fiber per mm^2)
   - distortion
   - percent of luminous energy transmitted

   Please indicate whether the hysteroscope has a tip articulation feature. Also, please indicate whether the field of view provided is for use in air or water.

Substantial Equivalence

2. In section III you compared characteristics of your system to the predicate device (Smith and Nephew Hysteroscope and Accessories – K013870). The predicate device that you have chosen has an optical design that uses a rod/lens whereas your system uses fiberoptics. Please provide an additional predicate device that uses fiberoptic technology comparable to the Interlace Medical Hysteroscope. Please provide a more comprehensive table that compares the characteristics of your device to the predicate devices. Please use the following example:

Characteristic	**Interlace Medical Operative Hysteroscopy System**	**Predicate Device**	**Predicate Device**
Dimensions			
Working Length			
Outer Diameter			
Working channel diameter			
Illumination			
Recommended light source			
Power rating of light source			
Optics			
Technology			
Depth of Field			
Direction of view			
Field of view in Air/Water			
Resolution			
Magnification			
Focal length			
Distortion			
# fibers			
Fibers per sq.			

mm			
Size of fiber core			
Area of active fiber per mm^2			
Pixel Count			
Thermal Specs.			
Max. Temp.			
Luminous energy transmitted			
Mechanics			
Tip Articulation			
Reusable or disposable			
How introduced			
RF Electrosurgical Features			

Labeling

3. You provided a copy of the Operating Manual in Attachment 1. There were deficiencies noted with respect to the indications, contraindications, warnings, and precautions. Please either make the following changes to the Operating Manual or provide a clinical justification for why they are not necessary:

    a. On page 32, please add the following sentence under Indications for Use: "Note: Hysteroscopes are used as tools for access to the uterine cavity and are not, in and of themselves, a method of surgery."

    b. On page 32, under Diagnostic Hysteroscopy, please add a bullet for" Intrauterine Foreign Body", delete "and pregnancy wastage", and add "or sonohysterogram" after "Evaluation of abnormal hysterosalpingogram."

    c. On page 32, under Operative Hysteroscopy, please add a bullet for "Endometrial Ablation", add the word "endometrial" before biopsy, and replace "Removal of submucous fibroids and large polyps" with "Polypectomy."

    d. On page 32 prior to "Contraindications to Hysteroscopic Myomectormy," please add the following section:

        Contraindications to Endometrial Ablation

        Hysteroscopic endometrial ablation, whether by laser or electrosurgery, should not be undertaken without adequate training, preceptorship, and clinical experience. Additionally, endometrial biopsy should be performed prior to any ablation. The following are clinical conditions that can significantly complicate hysteroscopic endometrial endometrial ablation:

        - Adenomatous Endometrial Hyperplasia
        - Uterine Leiomyoma
        - Severe Adenomyosis
        - Pelvic Pain (Subtle PID)
        - Uterine anomalies

e. On page 33, please change the title from "For Continuous Flow Hysteroscopy" to "For Continuous Fluid Flow Hysteroscopy" and please change the following text from:

"If liquid distension medium is used, strict fluid intake and output surveillance should be maintained."

to:

"If a liquid distension medium is used, strict fluid intake and output surveillance should be maintained to ensure that fluid deficit is known at all times. Depending on whether non-electrolyte or electrolyte solution is being used, when excessive fluid deficit occurs, consideration should be given to stopping further infusion and concluding the procedure".

f. On page 33, please change the title from "Potential Complications of Continuous Flow Hysteroscopy" to "Potential Complications of Continuous Fluid Flow Hysteroscopy" and add death to the list of potential complications.

g. Please add the following section after the section on potential complications of continuous fluid flow hysteroscopy:

For Continuous CO_2 Flow Hysteroscopy

If CO_2 gas is used as a distension medium, operative hysteroscopy is contraindicated due to the risk of gas embolization. CO_2 gas may be used for diagnostic procedures. It is extremely important that a hysteroscopic insufflator is used. Death has been reported when laparoscopic CO_2 insufflators were used during hysteroscopy. Flow of CO_2 should be limited to <100 mL/min, and intrauterine pressure should not exceed 100 mmHg.

Potential complications of Continuous flow hysteroscopy with CO_2:

- CO_2 embolization
- Circulatory collapse
- Death

h. On page 33, under Precautions, please add the following:

A thorough understanding of the principles and techniques involved in laser and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device and other medical instruments. Ensure that insulation or grounding is not compromised.

i. On page 33, please replace the current precaution wording regarding intrauterine fluid distension (second bullet) with the following:

Gravity fed intrauterine fluid distension can usually be accomplished with pressures in the rage of 35-75 mmHg. Hanging the fluid distention medium 42 inches above the patient can generate intrauterine pressure of approximately 80 mmHg. Unless the systemic blood pressure is excessive, it is seldom necessary to use pressures greater than 75-80 mmHg.

Cleaning and Sterilization

4. According to the guidance document, "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance (1996)", it is the responsibility of the original equipment manufacturer to provide the user with a cleaning and sterilization procedure that has been successfully validated. Although page 3 of your Operating Manual, briefly describes the cleaning process to be used on your device, the submission does not contain a description of how you

validated this process. For devices that are reusable between multiple patients, cleaning validation studies should be conducted using organic soil containing hemoglobin, protein and/or carbohydrate. Therefore, please validate your cleaning method and provide a detailed description of the method used and results observed. Please note that your results should indicate the levels of hemoglobin, protein and/or total organic carbon on your device before and after cleaning.*

5. Similarly, you have not fully described how you validated your sterilization method, (citing the standard used is not adequate). Therefore, please provide a detailed description of your sterilization validation process. This description should include a load configuration diagram showing where the devices are placed in the ethylene oxide (EtO) chamber and "worst-case" placement of at least 10 biological indicators on each device. In addition, please provide your raw data results. (Note that you should use at least three of your devices, or appropriate Process Challenge Devices, in your validation process.)* Your Contract Sterilizer should be able to provide you with this information.

6. Please provide the name and address of your contract sterilizer

7. Please clearly and appropriately label each of the parts of your device as reusable (non-sterile, to be cleaned and sterilized prior to each use) or single-use only (sterile, discard after single-use).

8. You indicate that the sterilization residuals levels after sterilization are as follows: EtO ≤ 20mg/day, Ethylene Chlorohydrin ≤ 12 mg/day. Please provide the exact values of these residuals.

9. You describe your device packaging as having a HDPE backing in a standard Tyvek/Mylar pouch. In addition, you indicate that, "the product will be labeled with an expiration date of 6 months from the date of sterilization and subsequently validated later to 2 years". However, you have not described the testing conducted to ensure that the sheath maintains its sterility for 6 months in "worst-case" storage conditions. Therefore, please provide descriptions of your package integrity and shelf life testing protocols used to provide this assurance.

   *For additional guidance on cleaning and sterilization of medical devices, you may refer to the following guidance documents that can be downloaded from the FDA website using the following link: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfggp/search.cfm

   - Updated 510(k) Sterility Review, Guidance K90-1; *Guidance for Industry and FDA; Document issued on: August 30, 2002)*
   - AAMI TIR30:2003 - A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices)
   - Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance (1996)
   - ANSI/AAMI/ISO 11135, 1994: Medical Devices-Validation and routine control of ethylene oxide sterilization.

Biocompatibility

10. On page 20 you provided a list of materials used in components either in the fluid path or in patient contact. Please provide more detailed descriptions of the patient contacting materials of the hysteroscope system including a drawing showing the location of the materials and the chemical abstract service numbers and manufacturers of the materials. Please indicate whether the patient contacting materials are identical to those used in the predicate devices and describe any colorants used. Also, please discuss whether there is possible interaction of the materials.

Also, please provide a description of the relative amounts of the materials in the predicate devices to those in the hysteroscope system and describe the whether the materials have similar types of patient contact. If sufficient information is not supplied, then biocompatibility testing including system toxicity may be required.

Electrical Safety and EMC Testing

11. You indicated on page 18 that the device meets the IEC 60601-2-18 standard for safety of endoscopic equipment. Please provide a copy of the test results showing the unit that was tested and the date of the report. Also, please provide the following leakage currents:
    - Enclosure leakage current
    - Patient leakage current

12. The submission does not address electromagnetic compatibility. Please either supply evidence of compliance with IEC 601-1-2 (or test results that guarantee a similar level of protection) or justify why this information is unnecessary.

Performance Testing

13. In section IV you provided information on safety for endoscopic equipment (IEC 60601-2-18), thermal safety, and optical resolution testing. You did not include a description of validation testing conducted on the product. Please provide a list of validation tests that are conducted on the product to ensure proper operation of the device.

14. Your submission indicates that the device will be used for both diagnostic and operative hysteroscopy. This means that the device must be used with an irrigation sleeve, laser equipment, and other ancillary instrumentation. Please provide specific descriptions of the ancillary equipment to be used with your hysteroscope for operative procedures. In addition, please describe what steps (including testing, if any) you have taken to ensure that these instruments are compatible with your hysteroscope.

XIII. Contact History

4/21/08 Requested and received electronic copy of submission.

XIV. Recommendation

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

Reviewer — Date: 5/9/08 VMP 5/9/08

Branch Chief — Date: 5/13/08

Draft: GBB 5/9/08

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

Date: May 8, 2008

From: Alison A. Cotterell, Ph.D.,
Microbiologist,
DRARD, OGDB

Subject: **K081070** – Interlace Medical Operative Hysteroscopy System
Sterility Consult Review

To: Glen B. Bell, Ph.D.
Biomedical Engineer
DRARD, OGDB

Applicant: Interlace Medical Inc.
139 Newbury St
Framingham, MA 01701

Contact: Ron Adams
Chief Technical Officer

Sterilizer: **Not Provided**

SCOPE OF REVIEW

This consult is limited to a review of the documentation of the sterilization processing and package integrity specific to the Interlace Medical Operative Hysteroscopy System.

REASON FOR SUBMISSION

The purpose of this 510(k) is to introduce the Interlace Medical Operative Hysteroscopy System into interstate commerce.

DEVICE DESCRIPTION

The Interlace Medical Operative Hysteroscopy System is for use in visualizing the uterine cavity and performing operative hysteroscopy procedures. The Operative Hysteroscopy System includes an obturator, a sheath and a hysteroscope. The obturator is used to facilitate introduction of the sheath into the uterine cavity. The single-use sheath includes a working

channel to permit the introduction of instrumentation. The reusable fiber optic hysteroscope is designed with optical lenses for visualization and optical fibers for illumination. The obturator is inserted into the working channel of the sheath and the hysteroscope is inserted into a designated lumen of the sheath. The Operative Hysteroscopy System can be combined with a hysteroscopic, fluid management system to provide continuous flow hysteroscopy capability. The hysteroscope can be used with standard camera couplers.

The Interlace Medical Operative Hysteroscopy System is a flexible fiberoptic scope, which functions by light being transmitted from a standard external high intensity light source through illumination fibers to the distal tip of the scope. The image is transmitted via an imaging bundle to an eyepiece. The image is viewed directly or transmitted through a video camera to a monitor. The Interlace Medical Hysteroscope is used with standard off the shelf light sources (Xenon or Metal Halide, up to 300 Watts).

INDICATIONS FOR USE

The Interlace Medical Operative Hysteroscopy System is used to provide viewing of the cervical canal and the uterine cavity in order to perform diagnostic and surgical procedures.

STERILITY

The Interlace Medical hysteroscope and obturator are reusable and will be supplied non-sterile. They must be sterilized by the user prior to use and before each reuse. The sheath is for single-use only and will have been sterilized using ethylene oxide gas, and validated 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, by a Contract Sterilizer. The sterility assurance level (SAL) for the sheath device will be 10^{-6}

The proposed cleaning and sterilization procedures are outlined below:

Cleaning

- Scrub using a cleaning brush (avoid optical surface)
- Soak in enzymatic cleaner (5 minutes, pH neutral)
- Rinse
- Check optical surfaces – distal tip, proximal window, fiber optic light post
- Use aluminum oxide powder to remove any deposits from optical surfaces (using cotton swab with water)

Sterilization

Sterilization Method: Ethylene Oxide (EtO)
Sterilant Concentration: (b)(4) Trade
Sterilization Residuals: EtO = < 20mg/day, Ethylene Chlorohydrin = < 12 mg/day
Cycle Parameters: 55°C, 35-70% relative humidity, 60 minutes exposure time, 11 hours aeration time)
Sterilization Validation Method: Overkill
Sterility Assurance Level: 10^{-6}
Package Description: HDPE backing in a standard Tyvek/Mylar pouch, (the product will be labeled with an expiration date of 6 months from the date of sterilization and subsequently validated later to 2 years)

Labeling Instructions
Interlace Medical includes the following labeling instructions for the user on page 3 of their operating manual:

> Follow standard hospital procedure maintaining the following parameters:
>
> Temperature: 131° ± 5° F (55° C)
> Relative Humidity: 35-70%
> Gas Concentration: ~ 736 mg/l
> Exposure Time: 60 minutes
> Aeration Time: 11 Hours
>
> IMPORTANT: It is recommended that the institution employs procedures which include the use of biological indicators in order to determine the effectiveness of the sterilization process.
>
> Sterilize the hysteroscope with ethylene oxide (Et0) gas, or other institution validated methods.

However, they do not provide a description of the process used to validate their device. According to the Guidance Document entitled, "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance (1996)", it is the responsibility of the Original Equipment Manufacturer (OEM) to provide the user with a sterilization procedure that has been successfully validated for use on the Interlace Medical Operative Hysteroscopy System, or a device similar in design and patient contacting materials.

CONCLUSION
Interlace Medical indicates that the Interlace Medical hysteroscope and obturator are reusable and will be supplied non-sterile, while the sheath is for single-use only and will be provided sterile. The sponsor provides an outline for the cleaning and sterilization procedures to be use on their device; however, this information is incomplete. Therefore, the sponsor should be asked to provide in depth protocols and validation methods for their cleaning and sterilization procedures so that we can better assess the efficacy of these methods.

RECOMMENDATION
I recommend that the following information be requested of the sponsor before a substantially equivalence decision be determined:

1. According to the guidance document, "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance (1996)", it is the responsibility of the OEM to provide the user with cleaning and sterilization procedure that has been successfully validated. On page 3 of your operating manual, you briefly describe the cleaning process to be used on your device; however, you have not described how you validated this process. For devices that are reusable between multiple patients, cleaning validation studies should be conducted using organic soil containing hemoglobin, protein and/or carbohydrate. Therefore, please validate your cleaning method and provide a detailed description of the method used and results observed. Please note that your results should indicate the levels of hemoglobin, protein and/or TOC on your device before and after cleaning.*

2. Similarly, you have not fully described how you validated your sterilization method, (citing the standard used is not adequate). Therefore, please provide a detailed

description on your sterilization validation process. This description should include a load configuration diagram showing where the devices are placed in the ehtylene oxide (EtO) chamber and "worst-case" placement of at least 10 biological indicators on each device). In addition, please provide us with all your raw data results. (Note that you should use at least three of your devices, or appropriate Process Challenge Devices, in your validation process.)*
(Your Contract Sterilizer should be able to provide you with this information).

3. Please provide the name and address of your Contract Sterilizer

4. Please clearly and appropriately label each of the parts of your device as reusable (non-sterile, to be cleaned and sterilized prior to each use) or single-use only (sterile, discard after single-use).

5. You indicate that the sterilization residuals levels after sterilization are as follows EtO = < 20mg/day, Ethylene Chlorohydrin = < 12 mg/day. Please provide the absolute values of these residuals.

6. You describe your device packaging as having a HDPE backing in a standard Tyvek/Mylar pouch. In addition, you indicate that, "the product will be labeled with an expiration date of 6 months from the date of sterilization and subsequently validated later to 2 years". However, you have not described the testing conducted to ensure that the sheath maintains its sterility for 6 months in "worst-case" storage conditions. Therefore, please provide descriptions of your package integrity and shelf life testing protocols used to provide this assurance.

*For additional guidance on cleaning and sterilization of medical devices, you may refer to the following guidance documents that can be downloaded from the FDA website using the following link: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfggp/search.cfm

- Updated 510(k) Sterility Review, Guidance K90-1; *Guidance for Industry and FDA; Document issued on: August 30, 2002)*
- AAMI TIR30:2003 - A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices)
- Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance (1996)
- ANSI/AAMI/ISO 11135, 1994: Medical Devices-Validation and routine control of ethylene oxide sterilization.

Reviewer: Alison Cotterell 5/9/08
Alison A. Cotterell, Ph.D. Date

Bell, Glenn

From: Ron Adams [Ron@InterlaceMedical.com]
Sent: Monday, April 21, 2008 11:26 AM
To: Bell, Glenn
Subject: RE: K081070 Interlace Medical - Interlace Medical Operative Hysteroscopy System
Attachments: TruthAccuracySigned.pdf; Appendix 0_FDA-36741.tif; Appendix 1_IFU 01-004_A.doc; Appendix 1_Therapeutic Sheath Pouch Label.pdf; Appendix 2_ACCESS_SHEATH.pdf; Appendix 2_ACCESS_SHEATH-SCOPE.pdf; Appendix 2_ACCESS_SHEATH-SCOPE_ASM.pdf; Appendix 2_drawing.pdf; Appendix 2_scope drawing.pdf; Appendix 3_K013870 SN.pdf; Appendix 3_SN IFU.pdf; Appendix 4A_FDA-3654_60601-2-18.doc; Appendix 4B_ScopeOptics.doc; Appendix 4B_ScopeThermal.doc; Cert form 3674.pdf; Fee Cover Sheet Sheath 510k.pdf; Premarket Cover Sheet_Scope.doc; Scope 510k Rev Final.doc

I believe this is everything contained in the submission. Please advise if it appears something is missing. The formats are those used to create or scan the documents.

Regards,

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

From: Bell, Glenn [mailto:Glenn.Bell@fda.hhs.gov]
Sent: Monday, April 21, 2008 10:11 AM
To: Ron Adams
Subject: K081070 Interlace Medical - Interlace Medical Operative Hysteroscopy System

Ron,

Would it be possible for you to email me an electronic copy of your 510(k) submission?

Sincerely,

Glenn

Glenn B. Bell, Ph.D.
Biomedical Engineer
FDA/CDRH/DRARD/OGDB
9200 Corporate Blvd.
Rockville, MD 20850
(240) 276-4106
FAX (240) 276-4156

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone

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

June 18, 2008

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

510(k) Number: K081070
Product: INTERLACE MEDICAL OPERATIVE HYSTEROSCOPY

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

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

Interlace MEDICAL

K081070/S1

June 13, 2008

JUN 17 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 K081070

Dear Mr. Bell,

The enclosed information is in response to FDA's May 15, 2008 request for additional information regarding the Interlace Medical Operative Hysteroscopy System (K081070).

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

Respectfully submitted,

Ron Adams
Chief Technical Officer

K70

Encl. Response Letter
Operating Manual
3654 Forms – ISO 17644, AAMI TIR-12, AAMI TIR-30, ISO 11135, ISO 10993-7
SPS Medical Cleaning Protocol 0806-122
(b) (4) [redacted]
Sheath Box and Package Labels
Hysteroscope Drawing
ETO Residual Protocol – STS #CA-002
Pouch Seal Validation Protocol
Shelf Life Protocol
Sheath Materials Drawing
Zibra QC Form
Distortion Photos

Interlace™ MEDICAL

Memo

To: Glenn Bell

From: Ron Adams

CC: Debbie Iampietro

Date: June 12, 2008

Re: Sheath/Scope 510k Response, K081070

The following is being submitted in response to FDA's letter dated May 15, 2008, requesting additional information on the Interlace Medical Operative Hysteroscopy System, K081070.

Device Description

1. In section II you provided a description of the Interlace Medical Operative Hysteroscopy System. Please provide a more complete description/characterization of the device. Please provide the following parameters:

   - fiberoptic imaging system description (# fibers, fibers per sq. mm, size of fiber core, area of active fiber per mm^2)
   - distortion
   - percent of luminous energy transmitted

   Please indicate whether the hysteroscope has a tip articulation feature. Also, please indicate whether the field of view provided is for use in air or water.

Reply: Please see the Substantial Equivalency Table - Appendix A.

Substantial Equivalence

2. In section III you compared characteristics of your system to the predicate device (Smith and Nephew Hysteroscope and Accessories – K013870). The predicate device that you have chosen has an optical design that uses a rod/lens whereas your system uses fiberoptics. Please provide an additional predicate device that uses fiberoptic technology comparable to the Interlace Medical Hysteroscope. Please provide a more comprehensive table that compares the characteristics of your device to the predicate devices

Reply: We have identified additional predicate devices that utilize fiberoptic technology as follows:

- Karl Storz Flexible Hysteroscope K961605
- Omnionics OMT Endoscope K991377
- Galileo Flexible Hysteroscope K974297, K981928

The completed Substantial Equivalency Table is included in Appendix A. Please note in many cases we are not able to supply certain details and specifications on the predicate devices as this information is not available through FOI – see Appendix A.

Labeling

3. You provided a copy of the Operating Manual in Attachment 1. There were deficiencies noted with respect to the indications, contraindications, warnings, and precautions.

Reply: Recommended changes were made to the Operating Manual. Please see revised Operating Manual enclosed.

Cleaning and Sterilization

4. According to the guidance document, "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance (1996)", it is the responsibility of the original equipment manufacturer to provide the user with a cleaning and sterilization procedure that has been successfully validated. Although page 3 of your Operating Manual, briefly describes the cleaning process to be used on your device, the submission does not contain a description of how you validated this process. For devices that are reusable between multiple patients, cleaning validation studies should be conducted using organic soil containing hemoglobin, protein and/or carbohydrate. Therefore, please validate your cleaning method and provide a detailed description of the method used and results observed. Please note that your results should indicate the levels of hemoglobin, protein and/or total organic carbon on your device before and after cleaning.*

Reply: Please see the attached 3654 Forms for ISO 17644, AAMI TIR-12 and TIR-30 Procedures for the Cleaning and Use of Reusable Medical Devices. We have contracted with an FDA Registered firm (b) (4) conduct these tests on a series of hysteroscopes. A copy of the cleaning protocol is enclosed. This testing will be completed prior to marketing the Interlace Medical device.

5. Similarly, you have not fully described how you validated your sterilization method, (citing the standard used is not adequate). Therefore, please provide a detailed description of your sterilization validation process. This description should include a load configuration diagram showing where the devices are placed in the ethylene oxide (EtO) chamber and "worst-case" placement of at least 10 biological indicators on each device. In addition, please provide your raw data results. (Note that you should use at least three of

your devices, or appropriate Process Challenge Devices, in your validation process.)* Your Contract Sterilizer should be able to provide you with this information.

Reply: Please see the attached 3654 Form for ISO 11135 Sterilization of Health Care Products, Ethylene Oxide: Requirements for development, validation, and routine control of a sterilization process for medical devices:2007. We have contracted with FDA Registered firms (b) (4) to conduct these tests on the sheath and (b) (4) hysteroscope. Copies of both of the ETO sterilization protocols are enclosed.

6. Please provide the name and address of the contract sterilizer for the sterile, single use sheath.

Reply: PROFESSIONAL CONTRACT STERILIZATION, Registration Number 1222313, 40 Myles Standish Blvd. Taunton, MA , 02780

7. Please clearly and appropriately label each of the parts of your device as reusable (non-sterile, to be cleaned and sterilized prior to each use) or single-use only (sterile, discard after single-use).

Reply: Both Box and Package labels on sheath incorporate the single-use graphic indicating that only one use is intended. We will add a label to the body of the hysteroscope indicating that it must be sterilized before use in a manner similar to the predicate device (K013870). Copies of the labels and a drawing of the scope are enclosed.

8. You indicate that the sterilization residuals levels after sterilization are as follows: EtO ≤ 20mg/day, Ethylene Chlorohydrin ≤ 12 mg/day. Please provide the exact values of these residuals.

Reply: The actual results will not be available until the sterilization validation is completed. The form 3654 is attached for ISO 10993-7 Biological Evaluation of Medical Devices, Part 7: Ethylene Oxide Sterilization Residuals. The results will be below the limits for devices of limited exposure as specified prior to marketing the device. The procedure for EO residual testing is included.

9. You describe your device packaging as having a HDPE backing in a standard Tyvek/Mylar pouch. In addition, you indicate that, "the product will be labeled with an expiration date of 6 months from the date of sterilization and subsequently validated later to 2 years". However, you have not described the testing conducted to ensure that the sheath maintains its sterility for 6 months in "worst-case" storage conditions. Therefore, please provide descriptions of your package integrity and shelf life testing protocols used to provide this assurance.

Reply: Copies of the test protocols for Pouch Seal Validation and Shelf Life (Accelerated Aging) are enclosed. Please note that we intend to drop the target

shelf life from 2 years to 1 year for the initial production products as outlined in the shelf life protocol.

Biocompatibility

10. On page 20 you provided a list of materials used in components either in the fluid path or in patient contact. Please provide more detailed descriptions of the patient contacting materials of the hysteroscope system including a drawing showing the location of the materials and the chemical abstract service numbers and manufacturers of the materials. Please indicate whether the patient contacting materials are identical to those used in the predicate devices and describe any colorants used. Also, please discuss whether there is possible interaction of the materials.

    Also, please provide a description of the relative amounts of the materials in the predicate devices to those in the hysteroscope system and describe the whether the materials have similar types of patient contact. If sufficient information is not supplied, then biocompatibility testing including system toxicity may be required.

Reply: Please see the Biocompatibility – Materials table (Appendix B) where we have provided additional details on the materials and the use in our device and the predicates. All of the components have either prior use in a specifically identified predicate device or have a well substantiated history of use in the medical device industry, with exposure to virtually all major tissue types. Since these materials has been previously shown to comply with ISO 10993, Interlace Medical therefore does not believe that further biocompatibility testing is needed to support this premarket notification.

Electrical Safety and Electromagnetic Compatibility Testing

11. You indicated on page 18 that the device meets the IEC 60601-2-18 standard for safety of endoscopic equipment. Please provide a copy of the test results showing the unit that was tested and the date of the report. Also, please provide the following leakage currents:

    - Enclosure leakage current
    - Patient leakage current

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

[redacted]

12. The submission does not address electromagnetic compatibility. Please either supply evidence of compliance with IEC 601-1-2 (or test results that guarantee a similar level of protection) or justify why this information is unnecessary.

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

[redacted]

Performance Testing

13. In section IV you provided information on safety for endoscopic equipment (IEC 60601-2-18), thermal safety, and optical resolution testing. You did not include a description of validation testing conducted on the product. Please provide a list of validation tests that are conducted on the product to ensure proper operation of the device.

Reply: The hysteroscope will undergo an inspection for Dimensional/Mechanical, Optical, Illumination and Labeling as outlined in the enclosed draft version of the (b)(4) Trade Secret Process - Product Specifications. The sheath will undergo pressure tests on both the inflow and outflow lumens to insure that no leakage is observed.

14. Your submission indicates that the device will be used for both diagnostic and operative hysteroscopy. This means that the device must be used with an irrigation sleeve, laser equipment, and other ancillary instrumentation. Please provide specific descriptions of the ancillary equipment to be used with your hysteroscope for operative procedures. In addition, please describe what steps (including testing, if any) you have taken to ensure that these instruments are compatible with your hysteroscope.

Reply: The sheath includes a [redacted] designed to accommodate the Interlace Medical Morcellator (K073690). The sheath includes integral irrigation lumen and lumens to facilitate its use for continuous flow hysteroscopy. The sheath is not designed to accommodate other ancillary equipment.

Appendix A
Substantial Equivalency Table

Characteristic	Interlace Medical Operative Hysteroscopy System	S&N Hysteroscope K013870	Storz Flexible Hysteroscope K961605	Galileo Flexible Hysteroscope K974297, K981928	Predicate Device K991377 OMT Endoscope
Dimensions					
Working Length	(b)(4) Trade Secret Process - Product Specifications	170 mm	240 mm	270 mm	≤ 150 cm
Outer Diameter		9 mm	3.6 mm	2.8 mm	1.0-2.5 mm
Working channel diameter		4 mm	1.33 mm	1.7 mm	Not specified
Illumination					
Recommended light source		Metal halide or Xenon	Not identified in Instruction Manual	Not specified -"std. external high intensity light source"	Not specified -"std. external high intensity light source"
Power rating of light source		≤300w			
Optics					
Technology		rod lens	fiber optic	fiber optic	Fiber optic
Depth of Field		3mm - ∞	5 – 20 mm	5 – 40 mm	5-40 mm
Direction of view		0°	0°	0°	0
Field of view in Air/Water		Air 88°	Air 88°	70° media unspecified	70
Resolution		7.1 line pairs/mm	4.0 line pairs/mm	USAF Grp 2 Element 5 or better	USAF Grp 2 element 5 or greater
Magnification		~1x @ 10mm object distance (excludes video camera)	~1x @ 10mm object distance (excludes video camera)	6.7X	7X
Focus Distance*		Est. 15 mm	Est. 15 mm	Unknown	Not specified
Distortion		See attached photo	See attached photo	Unknown	Not specified
# Image fibers**		N/A	Unknown	10k	Not specified

Appendix A
Substantial Equivalency Table

Characteristic	Interlace Medical Operative Hysteroscopy System	S&N Hysteroscope K013870	Storz Flexible Hysteroscope K961605	Galileo Flexible Hysteroscope K974297, K981928	Predicate Device K991377 OMT Endoscope
Image Fibers per sq. mm**	[redacted] (b)(4) Trade Secret Process - Product Specifications	N/A	Unknown	Unknown	Not specified
Size of fiber core		N/A	Unknown	Unknown	Not specified
Area of active image fiber per mm2 ***		N/A	Unknown	Unknown	Not specified
Pixel Count		N/A	Unknown	10k	10,000-50,000
Thermal Specs.					
Max. Temp.		Unknown	Unknown	Unknown	Not specified
Luminous energy transmitted ****		27%	0.8%	Unknown	Not specified
Mechanics					
Tip Articulation		No	Yes	No	Not specified
Reusable or disposable		Reusable	Reusable	Disposable	reusable
How introduced		Transcervical- access sheath/obturator	Transcervical – direct, no access sheath req'd	Transcervical – directly or with sheath	Natural body cavities or surgical incision through introducer, needle, catheter, etc.
RF Electrosurgical Features		None – intended for use w/ mechanical morcellator	None -Working channel can accept bx forceps	None -Working channel can accept 1.7 mm devices	Not specified

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

34

Appendix B
Biocompatibility – Materials Table

Interlace Medical

Operative Hysteroscopy System

Device Description

The Interlace Medical Operative Hysteroscopy System is intended for use in visualizing the uterine cavity and performing operative hysteroscopy procedures. The Operative Hysteroscopy System includes an obturator, a sheath and a hysteroscope. The obturator is used to facilitate introduction of the sheath into the uterine cavity. The single use sheath includes a working channel to permit the introduction of instrumentation. The reusable fiber optic hysteroscope is designed with optical lenses for visualization and optical fibers for illumination. The obturator is inserted into the working channel of the sheath and the hysteroscope is inserted into a designated lumen of the sheath. The Operative Hysteroscopy System can be combined with a hysteroscopic fluid management system to provide continuous flow hysteroscopy capability.
The hysteroscope can be used with standard O.R. camera couplers.

Indications for Use

Interlace Medical Operative Hysteroscopy System is used to provide viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

Note: Hysteroscopes are used as tools for access to the uterine cavity and are not, in and of themselves, a method of surgery.

Diagnostic Hysteroscopy

- Abnormal uterine bleeding
- Infertility
- Evaluation of abnormal hysterosalpingogram or sonohystogram
- Amenorrhea
- Pelvic Pain
- Intrauterine Foreign Body

Operative Hysteroscopy

- Directed Endometrial biopsy
- Polypectomy
- Submucous Myomectomy (see Contraindications)
- Transection of intrauterine adhesions
- Transection of intrauterine septa
- Endometrial Ablation

Contraindications

- Acute pelvic inflammatory disease

Hysteroscopy may also be contraindicated by the following conditions, depending on their severity or extent:

- Inability to distend uterus
- Cervical stenosis
- Cervical/vaginal infection
- Uterine bleeding or menses
- Known pregnancy
- Invasive carcinoma of the cervix
- Recent uterine perforation
- Medical contraindication or intolerance to anesthesia

Contradictions to Endometrial Ablation

Hysteroscopic endometrial ablation, whether by laser or electrosurgery, should not be undertaken without adequate training, preceptorship, and clinical experience. Additionally, endometrial biopsy should be performed prior to any ablation. The following are clinical conditions that can significantly complicate Hysteroscopic endometrial ablation:

- Adenomatous Endometrial Hyperplasia
- Uterine Leiomyoma
- Severe Adeomyosis
- Pelvic Pain (Subtle PID)
- Uterine anomalies

Contraindications to Hysteroscopic Myomectomy

Hysteroscopic myomectomy should not be undertaken without adequate training, preceptorship, and clinical experience. The following are clinical conditions that can significantly complicate hysteroscopic myomectomy:

- Severe anemia
- Inability to circumnavigate a myoma due to myoma size (e.g., predominantly

intramural myomas with small submucous components).

Warnings

- **For use only by physicians trained in hysteroscopy**
- **Do not use with High Frequency Electrosurgical devices**
- **Suspicion of pregnancy should suggest a pregnancy test before the performance of diagnostic hysteroscopy.**
- **The hysteroscope is shipped non-sterile. It must be thoroughly cleaned and sterilized according to validated infection control procedures before use/reuse. If scope light post adapters have been used, they need to be disassembled, cleaned, and sterilized before every subsequent use.**
- **Uterine perforation can result in possible injury to bowel, bladder, major blood vessels and ureter.**

For Continuous Fluid Flow Hysteroscopy:

- **If a liquid distension medium is used, strict fluid intake and output surveillance should be maintained to ensure that fluid deficit is known at all times. Depending on whether non-electrolyte or electrolyte solution is being used, when excessive fluid deficit occurs, consideration should be given to stopping further infusion and concluding the procedure.**

Potential Complications of Continuous Fluid Flow Hysteroscopy:

Hyponatremia
Hypothermia
Pulmonary edema
Cerebral edema
Death

For Continuous CO2 Flow Hysteroscopy

If Co2 gas is used as a distension medium, operative hysteroscopy is contraindicated due to the risk of gas embolization. Co2 gas may be used for diagnostic procedures. It is extremely important that a Hysteroscopic insufflator is used. Death has been reported when laparoscopic CO2 insufflators were used during hysteroscopy. Flow of Co2 should be limited to <100 mL/min, and intrauterine pressure should not exceed 100 mmHg.

Potential complications of Continuous flow hysteroscopy with CO2:

- **CO2 embolization**
- **Circulatory collapse**
- **Death**

- **High energy radiated light emitted from illuminating fiber at the distal end of the scope may give rise to temperatures exceeding 106° F/41° (within 8 mm in front of the scope). Do not leave tip of scope in direct contact with the patient tissue or combustible materials, as burns may result. Lower the light source output when working in close proximity to the object.**

- **The hysteroscope light post and adaptor may exceed temperatures of 41° C. Hysteroscopes should not be placed on the patient or on combustible materials, as burns may result.**

- **To prevent potential safety hazard to the patient caused by accidental loss of function of the device (i.e., front end damage by surgical instruments) it is recommend to have an additional sterile "stand-by" device during surgical procedures.**

- **Hysteroscopes can not be autoclaved. Autoclaving of scopes may result in irreparable damage. Low temperature sterilization methods or soaking disinfectant sterilization must be utilized.**

- **When scopes are used with laser equipment, appropriate filtering spectacles must be worn by the operating team. In some cases, a specific filter must be put between the scope and camera head to prevent camera damage by high-power laser radiation. Contact your laser supplier for details. To prevent scope damage by high-power laser radiation, always ensure that the laser delivery fiber is seen through the scope and not directed at the scope before energizing the laser.**

Precautions

℞

U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

- Vaginal ultrasonography before hysteroscopy may identify clinical conditions that will alter patient management.
- Gravity fed intrauterine fluid distension can usually be accomplished with pressure in the range of 35-75 mmHg. Hanging the fluid distention medium 42 inches above the patient can generate intrauterine pressure of approximately 80 mmHg. Unless the systemic blood pressure is excessive, it is seldom necessary to use pressures greater than 75-80mmHg.
- Prior to use, examine the device(s) for possible damage to assure proper functioning. If damaged, do not use.
- Avoid exposing the scope to sudden temperature changes. Do not immerse hot scopes into cold water or liquid.
- A thorough understanding of the principles and techniques involved in laser and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device and other medical instruments. Ensure that insulation or grounding is not compromised.

Inspection Prior to Use

Prior to each use, the outer surface of the insertion portion of the hysteroscope should be inspected to ensure there are no unintended rough surfaces, sharp edges or protrusions.

Hysteroscopy System Components

20-200 Therapeutic Sheath Assembly
20-901 Obturator
40-100 Fiber Scope Assembly – 0° DOV
40-101 Fiber Scope Assembly – 15° DOV
40-102 Fiber Scope Assembly – 30° DOV

Hysteroscope System Setup Instructions

The Interlace Medical Operative Hysteroscopy system consists of a sheath, obturator and hysteroscope as shown in Figure 1.

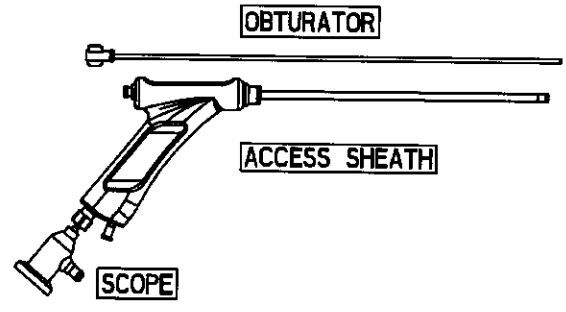


Figure 1. Hysteroscopy System

To place hysteroscope into sheath:

Insert the hysteroscope into the sheath, placing the light post of the hysteroscope into the slot of the sheath handle. Rotate the cam lock down to lock the scope in place. Reverse this process to remove the hysteroscope.

To place obturator into sheath:

Insert the obturator into the sheath utilizing the working channel of the sheath. Reverse this process to remove the obturator.

Sterilization

Hysteroscopes can not be autoclaved. Autoclaving of scopes may result in irreparable damage. Low temperature sterilization methods or soaking disinfectant sterilization must be utilized.

Hysteroscopes should be sterilized in a container which secures the instrument in place. Be sure the flexible shaft does not experience any undue forces or stress which can damage the delicate internal optics.

Sterilize the hysteroscope with ethylene oxide (Et0) gas, or other institution validated methods.

Ethylene Oxide (100% EtO) – wrapped)

Follow standard hospital procedure maintaining the following parameters:

Temperature:	131° ± 5° F (55° C)
Relative Humidity:	35-70%
Gas Concentration:	~ 736 mg/l
Exposure Time:	60 minutes
Aeration Time:	11 Hours

IMPORTANT: It is recommended that the institution employs procedures which include the use of biological indicators in order to determine the effectiveness of the sterilization process.

Hysteroscope Cleaning Instructions

Proper cleaning should be performed prior to sterilization.

- Light post adaptors must be removed prior to cleaning.
- Hysteroscopes should be soaked in an enzymatic, neutral pH cleaner for five minutes.
- Scrub all crevices using a cleaning brush to remove any visible debris from all crevices, taking care not to scratch any optical surface.
- Thoroughly rinse the scope to completely remove the cleaning solution.
- The scope has three optical surfaces that must be thoroughly cleaned and checked routinely to ensure both maximum transmission of illumination and a high-quality image.

  These are:
- The distal tip
- The proximal window or eyepiece
- The fiber optic light post

Removing Deposits from Scope Optical Surfaces

The aluminum oxide powder (REF XXXXX) is provided as an accessory to Interlace Medical scopes and is intended to be used, when required, to remove deposits on optical surfaces, thus maintaining optical integrity and allowing the scopes to perform as per their intended uses.

Note: Cleaning with aluminum oxide powder should only be performed when the image as viewed through the scope is cloudy, and not as part of your routine cleaning procedures.

To remove deposits, moisten a cotton-tipped swab with water. Dip the moistened swab into the aluminum oxide powder. Position the swab tip against the optical surface or the scope to be cleaned. While applying gentle pressure to the swab, scrub the window to remove any deposits. For smaller windows, rotate the swab instead of scrubbing. Rinse the optical surface with tap water and brush with a soft bristle brush while under running water to remove the aluminum oxide powder.

Note: Do not use any ultrasonic cleaning methods. The energy transmitted through fluid cavitations will damage seals and optical surfaces and will void the warranty.

Note: Foreign matter remaining on the fiber surface of the light post after cleaning may tend to burn and discolor the surface when exposed to a high intensity light source.

Hysteroscope Assembly/Disassembly Instructions

Interlace Medical Operative Hysteroscopes are compatible with Metal-Halide and Xenon light sources with up to 300 watts of power.

Place the correct adaptor on the light post of the fiber optic scope and on the instrument end of the light guide. Adapters are available for connection to Storz, Olympus, Wolf, and ACMI light sources as shown in Figure 2.

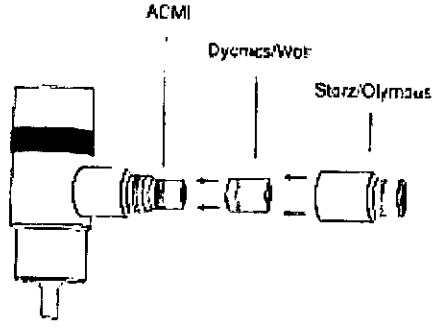


Figure 2 Light Post Adapters

The light post threads may be lubricated as needed, being sure to remove any excess lubricant as required. Make sure that the fiber optic surface remains free of foreign matter. Do not use tools to tighten the adapters – hand tighten only.

Maintenance

We recommend that you inspect the hysteroscope carefully before and after the procedure for possible signs of damage.

First, check the image quality of the scope by viewing the monitor. If image quality is impaired:

- Check the distal and proximal lenses of the hysteroscope for cracked or scratched lenses.
- Check the surface cleanliness of the distal and proximal lenses. A foggy or cloudy image can be the result of moisture entering the optical system or lack of cleanliness of exterior surfaces. When viewing reflected light, the surfaces should appear smooth and shiny

As a second step, check the illumination system of the scope. Reduced brightness can result from fiber damage:

- Check for fiber optic damage in the scope by holding the distal end of the scope toward a light and observing the light post on the hub. The center of the light post should appear clear or white. Noticeable black spots indicate serious damage to the fiber illumination bundle in the scope. This will affect light transmission and the brightness of the image viewed on the monitor.
- Check the light cable for damaged fibers by holding one end of the cable toward a light and observing the other end. Broken fiber will appear as black spots in the light field. A damaged light cable will affect its ability to transmit light and the brightness of the image viewed on the monitor.

Storage

Interlace Medical Hysteroscopes should be stored either in their shipping box or in a sterilization tray. In either case, proper care should be taken to ensure that the hysteroscope is immobile to prevent any damage.

New Product Warranty

The Interlace Medical Hysteroscopy System 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.

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 Program

Interlace Medical offers a 24-hour Service Replacement Program for its products to minimize downtime 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

FOR FURTHER INFORMATION

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

EC	REP

European Representative
Street Address
City, Postal Code
Country

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

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]

ISO 17644 - Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices:2004

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
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

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

' '7644 - STERILIZATION OF MEDICAL DEVICES — INFORMATION TO BE PROVIDED BY THE MANUFACTURER FOR THE
CESSING OF RESTERILIZABLE MEDICAL DEVICES:2004

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3, 4, 5, 6	See attached	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

Conformance is confirmed by (b)(4) who is performing the ETO steilization validation testing. (b)(4) is a registered FDA establishment - registration numbe(b)(4). Full conformance to the standard using the half cycle method is being claimed prior to marketing of the device

DESCRIPTION

See attached detail page.

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

S' 'TION 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.

ISO 17644 - Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices: 2004
Attachment Page

Sections 1, 2 are scope and definitions only – not applicable to form 3654

3 Information to be provided by the medical device manufacturer

3.1 Reprocessing instructions
At least one validated method for reprocessing the medical device shall be specified.
Complies prior to marketing

3.2 Limitations and restrictions on reprocessing
The manufacturer shall determine if processing in accordance with the provided instructions leads to a degree of degradation that will limit the useful life of the medical device. Where such degradation is established, the manufacturer shall provide an indication of the number of reprocessing cycles that can normally be tolerated, or some other indication of the end of the medical device's ability to safely fulfil its intended use.
Complies –included in IFU

3.3 Preparation at the point of use prior to processing
Requirements for preparation at the point of use to ensure satisfactory reprocessing of the medical device, shall be specified, if applicable.
Complies –included in IFU

3.4 Preparation before cleaning
Requirements for the preparation of the medical device prior to cleaning shall be specified if applicable. Where appropriate, instructions for at least the following procedures shall be given:
Complies –included in IFU

3.5 Cleaning
A validated method of manual cleaning shall be specified. At least one validated automated method using a washer-disinfector shall also be specified unless the medical device cannot withstand any such process, in which case a warning should be issued.
Complies prior to marketing

3.6 Disinfection
A validated non-automatic method of disinfection shall be specified. At least one validated automated method using a washer-disinfector shall also be specified unless the medical device cannot withstand any such process.
Not applicable – scope is specified to be sterilized by EO, not specified to be disinfected by non automatic methods

3.7 Drying
Where drying is necessary, a validated method of drying shall be specified. Where appropriate at least the following information shall be included:
Not applicable – scope is specified to be sterilized by EO, not specified to be disinfected by non automatic methods. Aeration time is specified.

3.8 Inspection, maintenance and testing
When methods are required at any stage of processing to confirm the cleanliness or performance or both, of the medical device, these shall be stated. Where particular maintenance actions are required during processing to ensure the proper performance and safety of the medical device, these shall be stated. Where appropriate, these shall include details such as any part or component that requires routine replacement and/or calibration and where necessary, details for return to the manufacturer or other qualified organization.
Complies –included in IFU

3.9 Packaging
If a specific method for packaging or containing the medical device during and after sterilization is required, it shall be stated and be compatible with the sterilization process and the medical device.
Complies –included in IFU

3.10 Sterilization
A validated method of sterilization shall be specified.
Complies prior to marketing

3.11 Storage
Any specific limitations for the time or conditions of storage of the reprocessed medical device prior to use shall be stated.
Not applicable – there are no limitations for the time or conditions of storage

4 Presentation of the information

4.1 Where applicable, the information required by clause 3 shall accompany the medical device, e.g. in the instructions for use supplied with the medical device, or on the medical device label or packaging.
Complies –included in IFU

4.2 The information specified in clause 3 shall take into account the nature of the medical device, its intended use and the knowledge and training of the persons involved in the processing.
Complies –included in IFU

4.3 The equipment or materials necessary in the specified processes shall be identified by its generic names or specification. Only in those cases where this does not provide sufficient information, trade names may be given in addition.
Complies –included in IFU

5 Validation of the reprocessing information provided
The manufacturer shall validate that any process identified in the information provided is capable of reprocessing the medical device for its intended use.
Complies prior to marketing

6 Risk analysis
In the risk analysis performed by the medical device manufacturer to determine the content and detail of the information to be provided, the medical device manufacturer shall take into account:

- the nature of the medical device;
- the intended use of the medical device;
- the likely training and knowledge of the processor;
- the equipment likely to be available to the processor.

Complies

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]

AAMI TIR 12:2004 "DESIGNING, TESTING AND LABELING REUSABLE MEDICAL DEVICES FOR REPROCESSING IN HEALTH CARE FACILITIES: A GUIDE FOR MEDICAL DEVICE MANUFACTURERS"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
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?	☒	☐
ɔs 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

47

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

'I TIR 12:2004 "DESIGNING, TESTING AND LABELING REUSABLE MEDICAL DEVICES FOR REPROCESSING IN HEALTH CARE ı ..LITIES: A GUIDE FOR MEDICAL DEVICE MANUFACTURERS"

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4, 6	See attached	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

Conformance is confirmed by (b)(4) who is performing the ETO sterilization validation testing. (b)(4) is a registered FDA establishment - registration number (b)(4). Full conformance to the standard using the half cycle method is being claimed prior to marketing of the device

DESCRIPTION

See attached protocol from (b)(4).

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

S.. TION 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]

AAMI TIR 30:2003 "A compendium of processes, materials, test methods and acceptance criteria for cleaning reusable medical devices"

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
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?	☒	☐
ɜs 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

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

TIR 30:2003 "A COMPENDIUM OF PROCESSES, MATERIALS, TEST METHODS AND ACCEPTANCE CRITERIA FOR CLEANING SABLE MEDICAL DEVICES"

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED*

Conformance is confirmed by (b)(4) who is performing the cleaning validation study. (b)(4) is a registered FDA establishment - registration number [redacted] Full conformance to the standard is being claimed prior to marketing of the device.

DESCRIPTION

See attached detail page.

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* 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]

ISO 11135-1:Sterilization of Health Care Products, Ethylene Oxide: Requirements for development, validation, and routine control of a sterilization process for medical devices:2007

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-228	
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?	☒	☐
ɜs 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

51

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

' '1135-1:STERILIZATION OF HEALTH CARE PRODUCTS, ETHYLENE OXIDE: REQUIREMENTS FOR DEVELOPMENT, VALIDATION, ... ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES:2007

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED*

Conformance with the standard is confirmed by (b) who is performing the sterilization validation. (b) is a registered FDA establishement - registration number [redacted] (Full conformance to the standard using the half cycle method is being claimed prior to marketing of the device.

DESCRIPTION

SAL 10-6 will be confirmed

JUSTIFICATION

See attached protocol

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]
ISO 10993-7 Biological Evaluation of Medical Devices, Part 7: Ethylene Oxide Sterilization Residuals

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-76	
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?	☒	☐
ɜs 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

53

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

[illegible]10993-7 BIOLOGICAL EVALUATION OF MEDICAL DEVICES, PART 7: ETHYLENE OXIDE STERILIZATION RESIDUALS

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED*

Conformance is confirmed by (b)(4) who is performing the ETO residual testing. (b)(4) is a registered FDA establishement - registration number (b)(4). Full conformance to the standard using a full cycle with aeration is being claimed prior to marketing of the device.

DESCRIPTION

Residual levels of EtO =<20mg/day, Ethylene Chlorohydrin =< 12 mg/day will be confirmed.

JUSTIFICATION

See attached protocol

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.

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

PROTOCOL

Confidential & Proprietary

Study No. (b)(4)

Effect of Cleaning and Decontamination of Interlace Medical Hysteroscopes

Prepared for:

Interlace™ Medical
139 Newbury Street
Framingham, MA 01701

Prepared by:

(b)(4) Trade Secret Process - Testing

Approved by:

(b)(4) Trade Secret Process - Testing

Ron Adams
Chief Technology Officer
Interlace™ Medical

Date

Study No.:	(b)(4) Trade Secret Process - Testing
Sponsor:	Interlace™ Medical 139 Newbury Street Framingham, MA 01701
Study Director:	(b)(4) Trade Secret Process - Testing
Study Personnel:	
Objective:	To verify the cleaning and decontamination process for the Hysteroscopes when employing the washing methodology as described by the manufacturer
Sample:	Interlace™ Medical Hysteroscopes (Table 1)

References:

1. United States Pharmacopeia Current Edition.
2. AAMI TIR12:2004 Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities. A Guide for Device Manufacturers 1st ed.
3. SPSmedical Internal Standard Operating Procedures.
4. Interlace™ Medical Operating Manual 01-004 Rev A
5. AAMI TIR30:2003 A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices

NOTICE: Any deviations from this protocol shall be documented. All protocols and reports are submitted to clients on a confidential basis. Test results are applicable only to the Test Samples that were tested within the limits of the testing procedures identified and are not necessarily indicative of the characteristics of any other samples. SPSmedical Supply Corp. shall not be liable under any circumstances for any amount in excess of the cost of the test(s) performed.

PROTOCOL
Study No. (b)(4) Trade Secret
Interlace™ Medical Hysteroscopes Cleaning Validation

1.0 INTRODUCTION:

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

5.0 ACCEPTANCE CRITERIA:

(b)(4) Trade Secret Process - Testing

6.0 CALIBRATION AND MAINTENANCE OF EQUIPMENT:

(b)(4) Trade Secret Process - Testing

7.0 DEVICE DAMAGE DISCLAIMER:

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

PROTOCOL

Confidential & Proprietary

Study No. (b)(4)

Ethylene Oxide Efficacy Validation Of Interlace Medical Hysteroscopes

Prepared for:

Interlace™ Medical
139 Newbury Street
Framingham, MA 01701

Prepared by:

(b)(4) Trade Secret Process - Testing

Approved by:

(b)(4) Trade Secret Process - Testing

Ron Adams
Chief Technology Officer
Interlace™ Medical

Date

PROTOCOL
(b)(4) Trade Secret Process - Testing
Interlace™ Medical Hysteroscopes ETO Efficacy Validation

Study No.: (b)(4) Trade Secret

Sponsor: Interlace™ Medical
139 Newbury Street
Framingham, MA 01701

Study Director: (b)(4) Trade Secret Process - Testing

Study Personnel:

Objective: To validate the Hysteroscopes for a 100% ETO Hospital Cycle.

Samples: Interlace™ Medical Hysteroscopes (Table 1)

References:

1. United States Pharmacopeia. Current Edition
2. AAMI TIR12:2004 Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities. A Guide for Device Manufacturers
3. ANSI/AAMI ST79:2006 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities
4. AAMI/ISO 14937:2000 Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices

(b)(4) Trade Secret Process - Testing

7. Interlace™ Medical Operating Manual 01-004 Rev A

(b)(4) Trade Secret Process - Testing

60

1.0 INTRODUCTION:

(b)(4) Trade Secret Process - Testing

2.0 JUSTIFICATION:

(b)(4) Trade Secret Process - Testing

3.0 EQUIPMENT AND MATERIALS:

(b)(4) Trade Secret Process - Testing

4.0 VALIDATION OF CULTURE MEDIA:

(b)(4) Trade Secret Process - Testing

5.0 VALIDATION OF SPORES:

(b)(4) Trade Secret Process - Testing

6.0 100% ETO HALF CYCLE DECRIPTION:

(b)(4) Trade Secret Process - Testing

7.0 PROCEDURE:

(b)(4) Trade Secret Process - Testing

8.0 ACCEPTANCE CRITERIA:

(b)(4) Trade Secret Process - Testing

9.0 CALIBRATION AND MAINTENANCE OF EQUIPMENT:

(b)(4) Trade Secret Process - Testing

10.0 DEVICE DAMAGE DISCLAIMER:

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

Interlace

REF 20-200

Contents – 1, Sheath (Therapeutic – 3 mm working channel)

Read Instructions Prior to Use

℞ only

STERILE EO

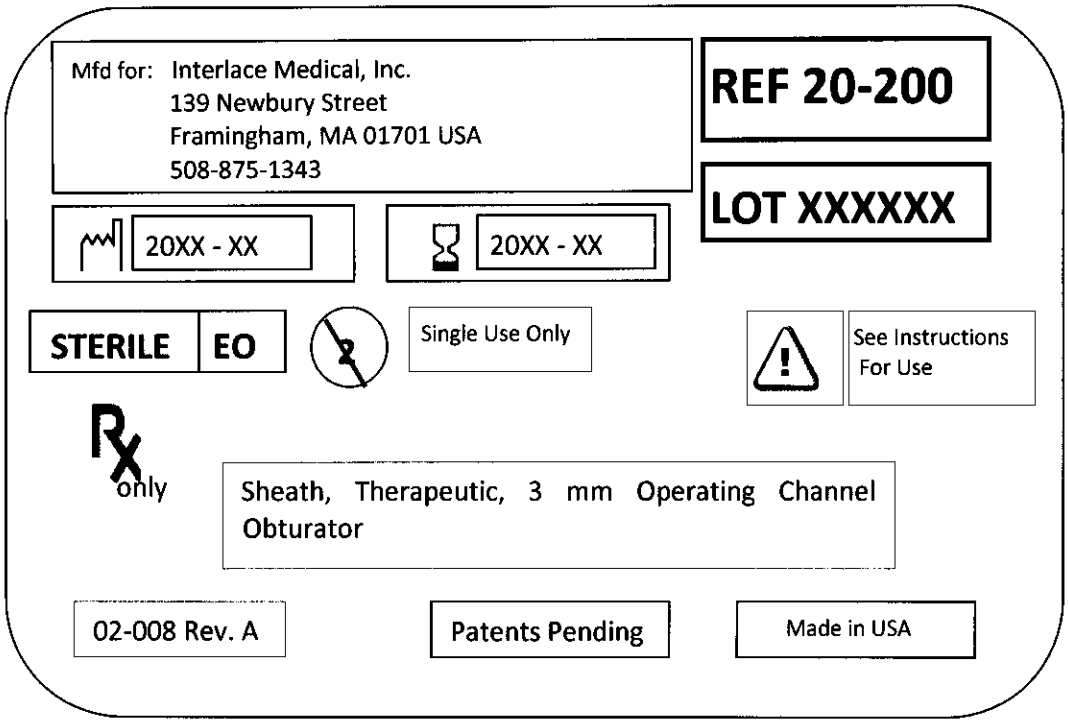
Single Use Only

XXXX-XX LOT XXXXXXX

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

Patents Pending

02-007 Rev A


Mfd for: Interlace Medical, Inc.
139 Newbury Street
Framingham, MA 01701 USA
508-875-1343
REF 20-200
LOT XXXXXX
20XX - XX
20XX - XX
STERILE EO
Single Use Only
See Instructions For Use
Rx only
Sheath, Therapeutic, 3 mm Operating Channel Obturator
02-008 Rev. A
Patents Pending
Made in USA

(b)(4) Trade Secret Process - Engineering Design

Revision : R-8
Effective Date: 3-8-07 Attachments: 0

Written By: [signature] Date: 2-21-07 Copies Distributed: QA, Chem

Analytical Chemistry: [signature] Date: 2-21-07

Quality Assurance: [signature] Date: 2-23-07

1 Purpose

1.1 To describe the analysis for EO residual by the headspace methodology.

1.2 Headspace analysis, the testing of the gas phase which is in equilibrium with a solid or liquid phase sample is a fast, simple and sensitive technique for the extraction and quantitative analysis of Ethylene Oxide (EO) residual levels found in EO-sterilized materials.

1.3 The method is often used when the more time-consuming methods involving extraction with organic solvents, such as acetone or dimethylformamide, leads to the extraction of contaminating materials which interfere with the analysis of EO.

2 References

2.1 Comparison of Analytical Methods for Residual Ethylene Oxide Analysis, S. J. Romano, J. A. Renner, J. of Pharmaceutical Sciences, Vol. 64, Vol. 8, 1975.

2.2 AAMI EOR 1986(Association for the Advancement Medical Instrumentation, Arlington, Va.)

2.3 SRP-002, Data and Quality Record

2.4 I-035, Operation of the Mettler Toledo AG285 Electronic Analytical Balance

3 Definitions

3.1 Headspace - the gaseous phase that remains in a sealed vial after heating.

4 Responsibility

4.1 Department management will ensure that this procedure is performed by trained technicians.

4.2 The technician is responsible for ensuring that these procedures are followed.

5 Materials

5.1 Screw-capped vials with Teflon - lined silicone-rubber septa. The volumes of the vials must be known to an accuracy of 0.05 ml, and are generally within the range of 7-10 mls. Vials having volumes outside of this range may be substituted at the request of the sponsor.

Note: Before use vials must be clean and dry and should be purged with dry nitrogen for at least one minute and immediately capped.

5.2 100 ul gas-tight syringe

5.3 Analytical balance with sensitivity of 0.1 mg

5.4 125 ml side-arm erlenmeyer flask

5.5 15-18 gauge hypodermic needles, 2 each

5.6 One foot lengths of latex tubing, 2 each

5.7 Beaker of water

5.8 Gas chromatograph, complete with carrier gas source, flame-ionization detector and chart recorder or digital data-collection device.

5.9 Gas chromatography column: 3.0% (by weight) Carbowax 20M on 80/100 mesh Chromosorb 101, or equivalent.

5.10 Ethylene oxide (greater than 99.5%)

5.11 Electronic spreadsheet AD-050

6 Procedure

6.1 Preparation of Standard Response Curve:

6.1.1 Obtaining a sample of pure Ethylene Oxide.
Note: This procedure must be carried out in an area vented directly to the exterior of the building.

6.1.1.1 Assembling the apparatus:

6.1.1.1.1 Attach a length of latex tubing (20-40 cm long) to the side arm of a 125 ml flask, and fit one of the two 16-18 gauge needles to the other end of the tube. Pierce the septum of a closed vial described in 5.1 with this needle and insert until the tip is as close to the bottom of the vial as possible. Now fit the remaining needle to the other length of latex tubing and also pierce the septum with this needle, but allow the tip of the needle to remain at the top of the vial. This arrangement will allow the relatively dense EO to displace the air in the vial and allow the air to escape through the upper needle.

6.1.1.2 Filling the vial

6.1.1.2.1 Next remove the pressurized container of pure (greater than 99.5%) EO from the refrigerator.

CAUTION

1. PURE EO IS HIGHLY FLAMMABLE

2. THE GAS IN THIS CYLINDER IS UNDER PRESSURE, AND THE AMOUNT OF THAT PRESSURE IS DEPENDENT UPON THE TEMPERATURE OF THE CYLINDER. FURTHER, THE CONTAINER IS CONSTRUCTED SUCH THAT LIQUID, NOT GAS, WILL BE RELEASED WHEN THE VALVE IS OPENED. IF THE TANK IS ALLOWED TO WARM, IT WILL BE IMPOSSIBLE TO CONTROL THE FLOW OF LIQUID ETHYLENE OXIDE INTO THE SIDEARM FLASK. IT BEHOOVES ONE, THEREFORE, TO WORK EXPEDITIOUSLY ONCE THE CYLINDER IS REMOVED FROM THE REFRIGERATOR.

6.1.1.2.2 Transfer about 5 ml of pure EO into the sidearm flask and stopper the flask immediately (rubber stopper). As the EO warms to room temperature and boils (NOTE: EO boils at 13.2°C or about 55°F) it will flush any residual air from the side-arm flask and then from the upright vial. Insert the outlet tube from the vial into a beaker of water and adjust the flow rate into the vial by gently warming or cooling the side-arm flask so that at least one bubble per second is visible in the beaker. Permit EO to flush through the apparatus just until all of the liquid EO has evaporated (10 - 15 minutes). The vial now contains pure EO at atmospheric pressure, and thus the contents have a concentration of 1.83 ug/ul according to the ideal gas law under conditions of 760 mm Hg atmospheric pressure and 20°C temperature.

6.1.1.2.3 **Note:** For the purposes of example the value of 1.83 mg/ml of EO at standard atmospheric pressure and room temperature conditions will be used. However, it may be necessary to calculate the exact value from the following equation:

$$EO\ (mg / ml) = (0.706)\ (P / 273 + T)$$

P= ambient atmospheric pressure in mm Hg

T= ambient temperature in °C.

6.1.1.3 Preparation of EO Dilution Series

6.1.1.3.1 Prepare two serial dilutions from this vial of pure EO and use the second of the dilutions for the generation of the standard curve. Make the dilutions by removing a volume M (in microliters) from the vial of pure EO with a gas-tight syringe and injecting it immediately into a second septum-sealed vial. Do not flush the syringe in this headspace. This step is carried out while EO

is flushing through apparatus. The EO concentration in the dilution vial is given by:

$$C = 1.83 \times M \times .001 / V$$

C= concentration of EO in ug/ul.

M= volume of concentrated EO in ul.

V= volume of dilution vial in ml.

and 0.001 is the factor to convert ug/ml to ug/ul.

6.1.1.3.2 A second serial dilution is then prepared from this vial containing diluted EO to yield a vial containing EO at concentration C^1, which is defined by $C^1 = C \times M^1 \times .001/V^1$:

C^1 = concentration of EO in ug/ul

M^1 = volume of EO at concentration C (the concentration in the first dilution) in ug/ul

V^1 = volume of the 2nd dilution vial in ml.

and 0.001 is the conversion factor for ml to µl.

6.1.1.3.3 Prepare a blank septum vial by purging a clean, dry vial with dry nitrogen for at least 1 minute then capping immediately.

6.1.1.3.4 Make duplicate 100 µl injections of the gas from the blank vial and duplicate injections of 10, 20, 30, 40, 50 and 100 ul from the second serial dilution vial onto the GC column. Typical G.C. conditions are as follows:

Column Temperature:	80°C
Injector Temperature:	200°C
FID Temperature:	210°C
Carrier Flow	35 ml/min

6.1.1.3.5 The peak areas are then measured and a regression line fitted to a plot of amount of EO injected (in micrograms) vs. peak area, using a least squares method.

6.1.1.3.6 The volumes M and M^1 are chosen such that

a) They are large enough to be measured accurately

b) The final concentration range of EO in the standard curve includes the expected EO concentrations of the samples tested.

6.2 Sample Preparation

6.2.1 Place the sample, the weight of which has been determined to ±0.1mg according to I-035, into a sample vial of known volume (as described in section 5.1), and place the vial and sample into an oven equilibrated at 100°C ± 3°C for at least 60 minutes. Other extraction temperatures and times may be substituted for these values at the request of the sponsor.

6.2.2 Remove the vial from the oven and immediately inject one or more 100 µl aliquots of the gas phase into the GC.

6.2.2.1 With some samples, delay following heating may permit the sample to reabsorb EO, leading to erroneously low values. Measure and record the area associated with the EO peak. If injections result in decreasing EO peak response, it is possible that reabsorption of EO by the sample is occurring. It may therefore be necessary to reheat the sample to 100°C and inject the head space at this temperature in order to achieve consistency.

6.2.2.2 If the area of the sample peak for a 100µl injection exceeds that of the most concentrated standard in the curve, reduce the sample injection volume (to 50 µl or less if necessary) until the peak area is within the standard curve. On the chromatogram, record the sample volume injected and use the correct sample volume in the calculations in 8.2.2.

6.2.2.3 It is unusual for second and subsequent heatings to require a sample volume less than 100µl.

6.2.3 After reproducible measurements have been achieved, take the vial to a fume hood. Open the vial and flush the interior with dry nitrogen for a minimum of 1 minute. Seal the vial with a fresh Teflon lined septum.

6.2.4 Repeat steps 6.2.1 through 6.2.3 to determine the amount of EO remaining with the sample..

6.2.5 The cycle of vial flushes, resealing, heating and GC analysis is repeated until the amount of EO measured is less than 10% of the value found in the first heating.

7 Recording of Results

7.1 Record all weights, volumes and instrumental data in a laboratory notebook according to SRP-002.

8 Calculations

8.1 Example Calculation for standard concentration:

8.1.1 Assume 100 ul of EO is removed from the vial containing pure EO, i.e., M=100, and injected into a vial of volume 8.8 ml (V=8.8). Substituting these values into the first equation:

$C = 1.83 \times M \times 0.001/V$

$= 1.83 \times 100 \times 0.001/8.8$

$= 0.0208$ ug/ul

8.1.2 Assume that the second serial dilution is identical to the first ($M^1 = 100$, $V^1 = 8.8$. Then the final EO concentration is given by:

$C^1 = 0.0208 \times 100 \times 0.001/8.8$

$= 0.000236$ µg/µl

$= 0.236$ ng/µl

8.1.3 The amounts of EO injected for the standard curve will therefore be:

100µl x .000ng/µl = 0 ng

10µl x .236ng/µl = 2.36 ng

20µl x .236ng/µl = 4.72 ng

30µl x .236ng/µl = 7.08 ng

40µl x .236ng/µl = 9.44 ng

50µl x .236ng/µl = 11.8 ng

100µl x .236ng/µl = 23.6 ng

These values are used as the abscissa for the standard curve.

8.2 Calculations for sample concentrations

8.2.1 If the weight EO reported on the chromatograms is greater than 2.36 nanograms, use electronic spreadsheet AD-050 for calculations.

8.2.1.1 Enter sample weight and volume from notebook.

8.2.1.2 Enter nanograms EO released from chromatograms

8.2.1.3 The spreadsheet, AD-050 will calculate the total residual EO in each sample.

8.2.2 If weight EO is 2.36 nanograms or less or if the electronic spreadsheet is unavailable, record in a laboratory notebook (SRP-002) the weight EO (in nanograms) for each sample injection from the chromatograms.

8.2.2.1 Calculate the total weight EO released in each heating using the following equation.

$$\text{Weight EO/heating (in nanograms)} = \frac{EO \times V}{(J)}$$

Where: EO is the weight (ng) EO from the chromatograms

V is the volume of the extraction vial in milliliters

J is the sample injection volume in milliliters

8.2.2.2 For each sample determine the total weight EO released after exhaustive extraction by adding the weights determined 8.2.2 for all of the heatings.

8.2.2.3 Use the following formula to calculate the concentration EO in each sample.

$$\text{ppm EO} = \frac{NG}{(W)}$$

NG is the weight in nanograms of EO from 8.2.3

W is sample weight is in milligrams

8.2.2.4 Calculate the dosage in milligrams using the following formula.

$$\text{Dosage (mg/device)} = \frac{\text{ppm} \times W}{1000}$$

ppm is value calculated in 8.2.4

W is the weight of ONE device in grams

1000 is the conversion factor for grams to milligrams

9 Revision History

The following are approved changes incorporated into revision numbers indicated below	
Revision	**Description of Change**
7	Editorial – put document into current format Editorial - 2.5 added reference STS I-035 Technical - Section 6.2 rewritten to clarify when reduced sample injection volumes are required Technical –Section 8.2 totally rewritten to clarify calculations.
8	Periodic review Updated format to comply with current procedure Updated References Purpose rewritten for clarity Added use of electronic spreadsheet for calculations step 8.2.1

PACKAGE VALIDATION PROTOCOL/SHEATH

Approvals:

Engineering: _____ Date: _____

Quality Assurance: _____ Date: _____

Operations: _____ Date: _____

TITLE: Pouch Seal Packaging Validation

OBJECTIVE: The objective of this protocol is to substantiate and document that the pouch/seal packaging provides effective and consistent seals which will maintain the intended sterile barrier for the product. The protocol is designed to comply with ISO 11607 Packaging for Terminally Sterilized Medical Devices. Tensile testing should be conducted in accordance with ASTM F88-99, Standard Test Method for Seal Strength of Flexible Barrier Materials

SCOPE: This validation will encompass the operational qualification (process challenge) and the performance qualification (nominal operating parameters). This validation will qualify the sealing process for the pouch seal at the operating parameters.

The operating parameters (time, temperature and pressure) are controlled with calibrated PLDs such that package testing at only the specified parameters, and not at both the minimum and maximum operating parameters, is sufficient.

Samples will be tested both before the sterilization cycle and after the sterilization cycle. This will ensure sterilization does not adversely affect seal strength integrity. Pouch sealing process will be assessed by seal integrity, width, tensile testing, and dye penetration or burst testing. Aging and transit testing of the pouch will not be studied here, as it will be established and verified in the product accelerated aging study.

DEFINITIONS: None

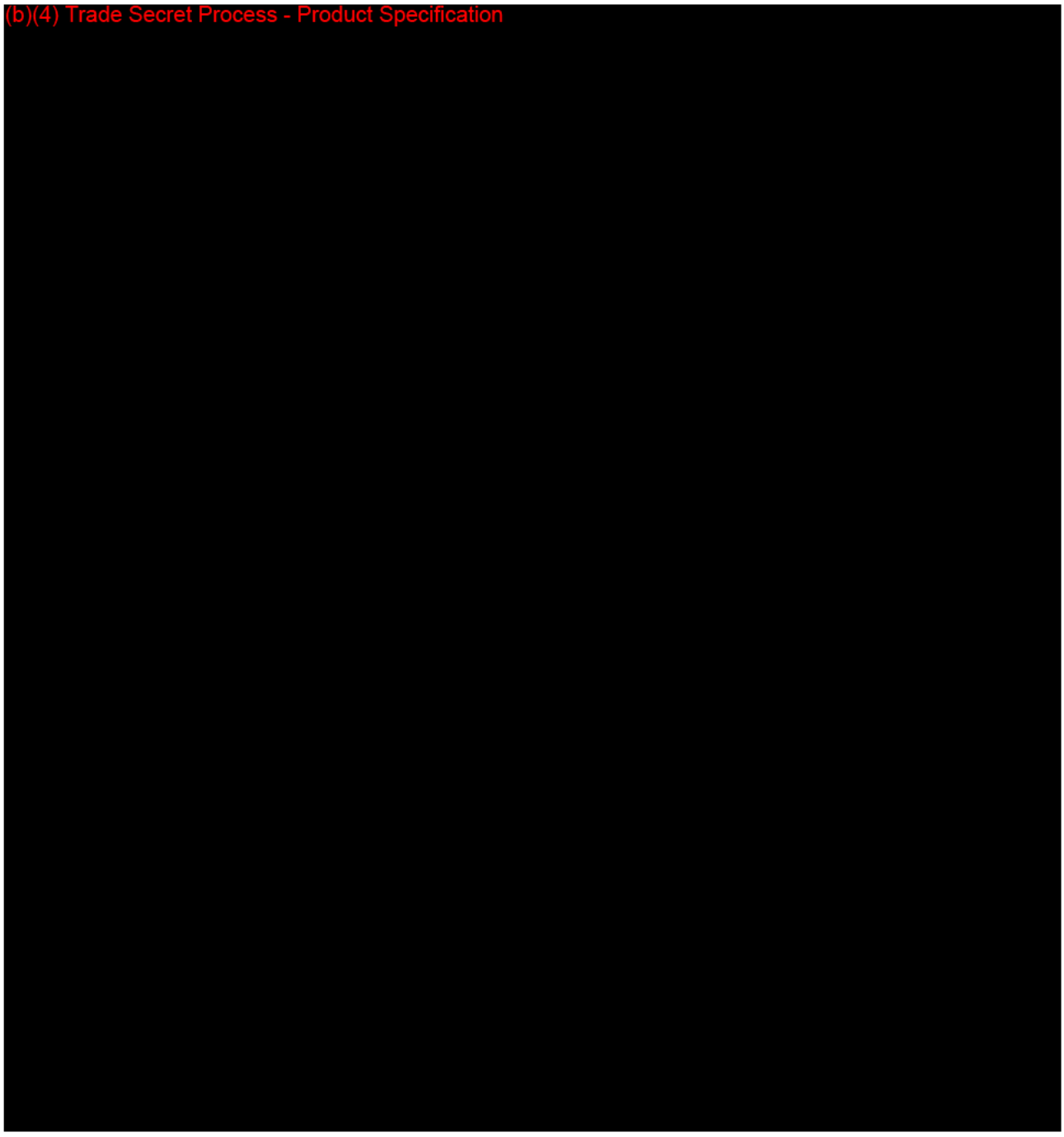
REFERENCES: ISO 11607 Packaging for Terminally Sterilized Medical Devices
ASTM F88-99, Standard Test Method for Seal Strength of Flexible Barrier Materials

EQUIPMENT: Tensile Tester
DT Industries 24AS/2 Heat Sealer

RESPONSIBILITY: QA - Protocol and report originator, approval
Operations - Execution of protocol, testing

PROCESS VARIABLE INPUTS:

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



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

The following tables outline the sample size requirements:

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

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

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

DYE PENETRATION TEST

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

REVALIDATION: Re-validation will be necessary if the process, materials, or equipment is altered in a way that could affect packaging or product quality.

ATTACHMENTS: All inspection results, data sheets, sterilization reports shall be attached to the final report.

Test Protocol: SHEATH Shipping and Accelerated Aging

Approval Signatures:

Operations	Date
Quality Assurance	Date
Engineering	Date

1.0 PURPOSE

The purpose of this document is to define the test methods and acceptance criteria required to perform product qualification testing on the Sheath. The testing is also intended to evaluate the effects of aging on the performance characteristics of the Sheath and package.

2.0 SCOPE

The scope of this document encompasses a test protocol which defines the test methods and acceptance criteria, required to perform accelerated age testing on the Sheath. Testing defined in this protocol includes visual examination, dimensional inspection, and functional testing after environmental exposures equivalent to 0 (base line), 6 and 12 months of shelf life.

3.0 DEFINITIONS

Accelerated Aging - A technique to simulate the effects of aging by subjecting the product to conditions that may be considered extreme or greater than what the product may in fact be subjected to during its expected life.

Acceleration Factor - Also known as Q_{10} factor. A multiplication factor utilized as part of the equation used to estimate the product shelf life based on accelerated studies. The typical relationship selected for commonly used medical polymers is $Q_{10} = 2$. That is, a doubling of the reaction rate for each 10°C increase in the temperature above the use or storage temperature.

Ambient Conditions - Common storage conditions that a product could reasonably expect to see during storage. On an average this is considered to be 22°C (between 20°C to 25°C).

Shelf life - The term or period during which a product remains suitable for the intended use.

Visual Inspection - To examine, without magnification, under normal lighting from a distance of 10 to 12 inches.

4.0 REFERENCE DOCUMENTS:

- Product Functional Specification
- Product Drawings
- ISTA Procedure 2A. Performance Test for Individual Packaged Products Weighing 150 lb. (68 kg) or Less.
- ISO 11135: 2007, Medical Devices-Validation and Routine Control of Ethylene Oxide Sterilization
- ISO 11607, Packaging for terminally sterilized medical devices.
- ASTM F 1980-99 – Standard Guide for Accelerated Aging of Sterile Medical Device Packages

5.0 RESPONSIBILITIES:

The following will be involved and responsible for the implementation of this protocol

- Operations — Manufacturing, Packaging and Testing
- QA — Protocol generation and approval
- PCS — Sterilization
- Supplier — ISTA Project 2A Transportation Testing
- Supplier — Package Tests

6.0 REQUIREMENTS:

Test Sample Traceability

All samples tested under this plan will be built from traceable components unless explicitly noted. All material used for this protocol will be in conformance to established specifications. All manufacturing will be performed using controlled, documentation, i.e. approved drawings, BOM/routing forms, processes, and inspection procedures.

Test Sample Documentation

The design and manufacturing process of all samples tested under this plan will be documented.

Design Verification Testing Protocols

Individual test protocol(s) and/or methods shall adequately describe test objective, scope, success criteria, test sample history, testing equipment and methodology, data to be collected, and method of data analysis.

Training

Assembly and test personnel are to be trained in the manufacturing procedures and on the handling of the probes. They are to be trained in the use of the test equipment. This training will be documented.

Calibration

All test and manufacturing equipment is to be calibrated

7.0 TEST PLAN:

All products will undergo sterilization and aging prior to testing. By selecting products which have been processed through manufacturing, sterilization, aging, conditioning, and simulated shipping and handling, and then subjecting them to product performance and sterile barrier tests, it can be determined if the production process and packaging designs are adequate to maintain product performance and sterile conditions throughout the expected shelf life of the product.

Design Verification

Mechanical, dimensional, functional and simulated use testing in accordance with section 11.

Design Validation
Design validation testing will be conducted prior to release.

Manufacturing Validation

- Process Validations: Process validation will be completed for manufacturing processes which are inherently variable and cannot be verified through inspection.
- Packaging Validation: Sterile packaging will be validated
- Sterilization Validation: Devices will be sterilized using ethylene oxide gas. A contract sterilization company will perform the validation per contractually established guidelines. Validation of this method will be accomplished using a protocol consistent with the overkill approach described in ANSI/AAMI/ISO 11135: 2007, Medical Devices-Validation and Routine Control of Ethylene Oxide Sterilization. The sterility assurance level (SAL) for the device is 10^{-6}.
- Ship Testing will be completed to ensure that the product packaging sufficiently protects the devices during shipping.

8.0 SAMPLE SIZE RATIONALE:

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

[redacted]

9.0 SAMPLE PREPARATION:

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

[redacted]

10.0 ACCELERATED AGING CRITERIA:

10.1 Aging Methodology

The method used to determine the temperature exposure and duration is based on the Arrhenius model and is known as the Simplified Protocol for Accelerated Aging.

The following formula is used to calculate the exposure time.
$TIME_{T1} = TIME_{Rt} / Q_{10}^{(T1 - TRt) / 10}$

Where:
T_1 = Oven aging temperature,
T_{Rt} = Room temperature = Ave. 22°C (Ambient/use /storage)
Q_{10} = Reaction rate coefficient (This is usually 2, unless another proven rate coefficient has been previously determined)
$TIME_{Rt}$ = Time period of exposure to Oven Temperature Equivalent to Shelf Life
$TIME_{T1}$ = Ambient shelf-life Age (e.g. 26 weeks, 1 yr, 3 yrs, etc)

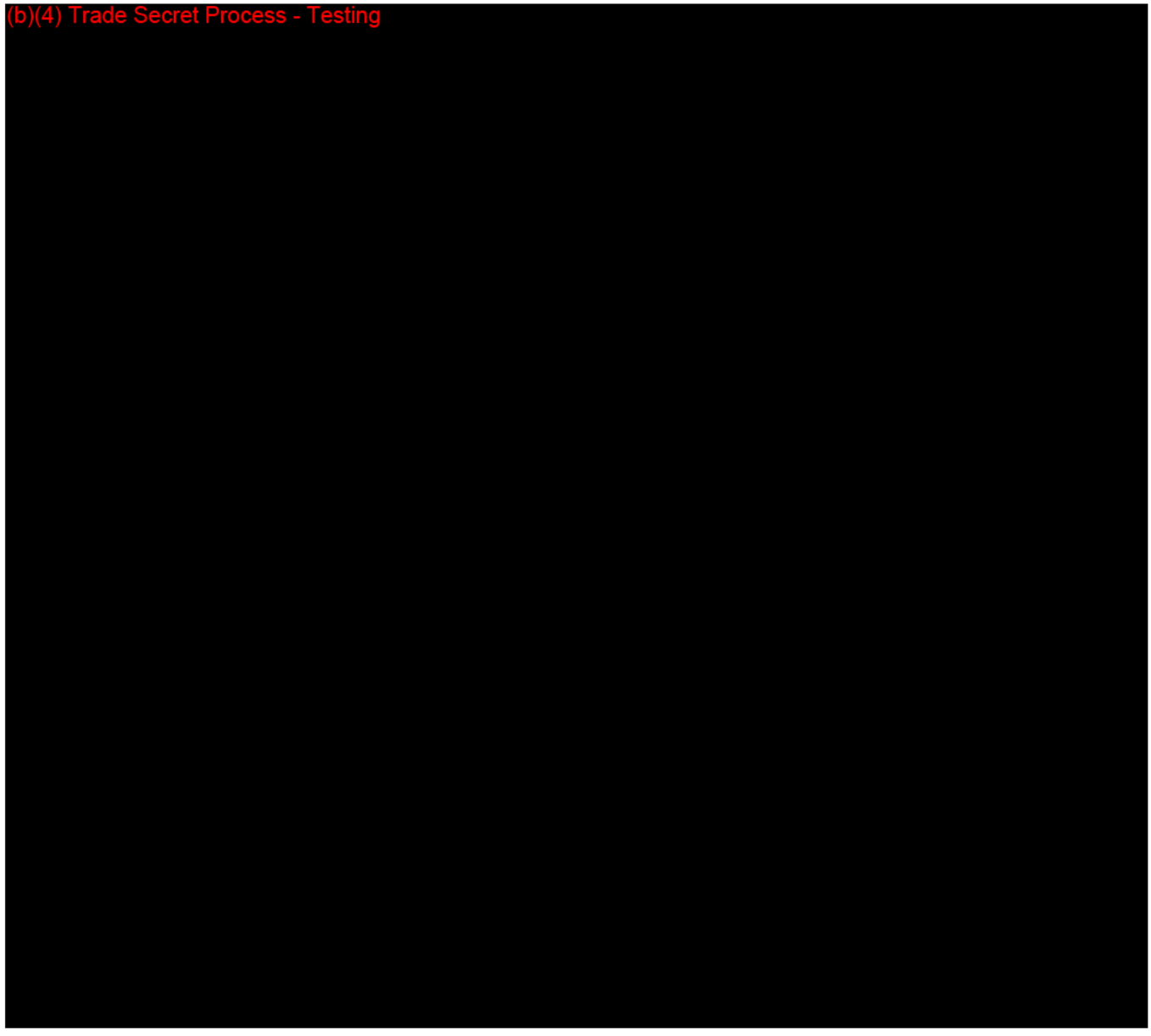
The actual product in normal storage and use conditions is expected to be exposed to ambient temperatures between 20°C and 25°C (Average 22°C = 72°F). As such, 22°C shall be used as ambient temperature (T_{Rt}).

The accelerated temperature selected of 55°C shall be taken as the maximum temperature for exposure of devices.

Based on the formula above, various periods of exposure to several oven temperatures (maximum 55°C) are calculated for various true shelf-life periods. Table 1 reflects this data.

TABLE – 1: ACCELERATED AGE TESTING PARAMETERS

(b)(4) Trade Secret Process - Testing



11.0 TESTS REQUIRED:

11.1 Visual Inspection

All samples from each group shall be inspected before and after the exposure to accelerated aging temperatures. The purpose of the Visual Inspection is to demonstrate that manufacturing, sterilization and exposure to accelerated aging temperatures do not cause any visually evident defect(s) to the Sheath.

Obtain samples at applicable interval (baseline, 6 and 12 months). Visually inspect the samples for evidence of damage and/or material degradation.

11.2 Dimensional Inspection

Upon completion of the visual inspection, mark each sample with the number on the pouch. Measure Sheaths from each group for dimensional parameters per drawing. Record the observations in an appropriate laboratory notebook.

11.3 Functional Testing

(b)(4) Trade Secret Process - Testing

[redacted]

11.4 Sterile Barrier Testing

This test will be performed on the 1 year aged group and be performed prior to any of the visual and functional tests being performed. The package will be visually inspected for any product damage. After visual inspection is completed all pouches will be tensile tested and dye penetration tested. The devices will then be subjected to the tests in 11.1 through 11.3 above.

11.5 Ship Testing

(b)(4) Trade Secret Process - Testing

[redacted]

12.0 ACCEPTANCE CRITERIA:

All samples must meet the specification defined in the product specification and/or drawings as applicable. In the event any failures are identified during the testing, the testing process will continue to identify the magnitude of the failure within the sample and a root cause analysis shall be conducted. Corrective action will be determined, initiated, and documented.

Results after each test stage will be reviewed and approved. Results of real-time aging will be compared to accelerated results when available. The accelerated results are intended to be predictive in nature. As the accelerated aging process exposes the product to conditions not normally seen in normal aging which may introduce unforeseen failure modes, the real-time results shall take precedence.

(b)(4) Trade Secret Process - Testing

[redacted]

Primary packages will be visually inspected for damage caused by conditioning. Packages may incur slight physical or cosmetic damage during this conditioning

such as scuff marks, dents, bent corners etc. Print may be skewed or lightly angled, but must contain complete and legible character information.

For sterile barrier testing, the package will be considered to pass this study if no dye passes through the sterile barrier and passes the 100% visual and tensile inspection for seal and package integrity and the aged product shows substantial equivalency to the baseline results. All tensile values must be above 1 lb.

Product performance test results of aged product will be compared against the baseline testing results.

13.0 RECORDS:

Upon completion of the testing, a report will be compiled indicating the success or failure of the protocol. Any failures and all data collected during the testing will be included in the report. The original report and protocol will be retained in the design history file. Two reports will be generated. The first will be the results of the accelerated aging and the second will be the results of the real time aging.

The following information shall be attached to the summary report:

Sterilization records
Raw test data
Outside lab test reports

(b)(4) Trade Secret Process - Engineering Drawing

(b)(4) Trade Secret Process - Engineering Drawing

(b)(4) Trade Secret Process - Engineering Drawing

(b)(4) Trade Secret Process - Engineering Drawing

(b)(4) Trade Secret Process - Engineering Drawing

(b)(4) Trade Secret Process - Engineering Drawing

(b)(4) Trade Secret Process - Engineering Drawing