K073690

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

APR 17 2008

1. Sponsor Name

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

2. Device Name

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

3. Identification of Predicate or Legally Marketed Device

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

4. Device Description

The system consists of the following components:

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

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

5. Intended Use

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

6. Comparison of Technological Characteristics

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

7 Performance Testing

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

8. Statement of Equivalency

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 17 2008

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

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

Dear Mr. Adams:

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

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

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

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

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

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

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

Enclosure

Indications for Use

510(k) Number (if known): K073690

Device Name: Interlace Medical Hysteroscopic Morcellation System

Indications For Use:

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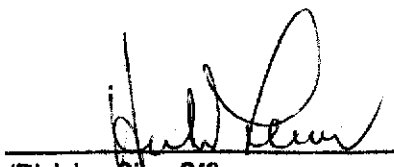
Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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