May 10, 2019

Shanghai AnQing Medical Instrument CO., Ltd.
Lina Fei
Quality Manager
150 Cailun Road, Zhangjiang High-Tech Park
Shanghai, 201210
China

Re: K181545
Trade/Device Name: Hysteroscope System
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: II
Product Code: HIH
Dated: April 3, 2019
Received: April 10, 2019

Dear Lina Fei:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sharon M. Andrews -S

Sharon M. Andrews
Assistant Division Director
DHT3B: Division of Reproductive, Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Indications for Use

The Hysteroscope System is intended to be used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures. Note: Hysteroscopes are used as tools to access the uterine cavity and are not, in and of themselves, a method of surgery.

Generally recognized indications for diagnostic hysteroscopy include:
- Abnormal bleeding
- Infertility and pregnancy wastage
- Evaluation of abnormal hysterosalpingogram
- Intrauterine foreign body
- Amenorrhea
- Pelvic pain

Generally recognized indications for operative hysteroscopy include:
- Directed endometrial biopsy
- Polypectomy
- Submucous myomectomy
- Transection of intrauterine adhesions
- Transection of intrauterine septa
- Endometrial ablation

Type of Use (Select one or both, as applicable)
- [ ] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

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

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
510(k) Summary – K181545

I. Submitter
Device submitter: Shanghai AnQing Medical Instrument CO., Ltd.
Room 202, 2nd Floor, No.7 Building & Room 202, 2nd Floor No.4 Building,
150 Cailun Road, Zhangjiang High-Tech Park, 201210, Shanghai, China

Contact person: Wen Shi
Quality Manager
Phone: +86 135 8580 5802
Fax: +86 21 5019 1132 – 8004
Email: wenshi@innovexmed.com.cn

Date prepared: May 9, 2019

II. Device
Trade Name of Device: Hysteroscope System
Common Name: Hysteroscope (And Accessories)
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: II
Product Code: HIH
Product Code Name: Hysteroscope and Accessories

III. Predicate Devices
Trade name: LiNA OperaScope
Common name: Hysteroscope
Classification: 21 CFR 884.1690 Hysteroscope and Accessories
Product Code: HIH, Hysteroscope and Accessories
Premarket Notification: K171113

The predicate device has not been subject to a design-related recall.

IV. Device description
The Hysteroscope System consists of a sterile single-use disposable Rigid Hysteroscope and video processor for clinical image processing. The Rigid Hysteroscope (available in models GSA01-B, GSB04-B and GSB14-B) are used to permit direct viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures. Model GSA01-B is intended for diagnostic hysteroscopy only, and has a rigid
shaft without operative channel (injection channel only). Models GSB04-B and GSB14-B are intended for both diagnostic and operative hysteroscopy, and have an operative (insertion) channel. GSB04-B has a rigid shaft, and GSB14-B has a curved tip. The specifications for the three models are as follows:

<table>
<thead>
<tr>
<th>Model</th>
<th>Shape</th>
<th>Scope diameter</th>
<th>Working length</th>
<th>Minimum insertion channel diameter</th>
<th>Injection channel Diameter</th>
<th>Tip Curve</th>
<th>Curved Tip length</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSA01-B</td>
<td>Straight</td>
<td>Φ4.0mm +0.0/-0.3mm</td>
<td>260mm±8mm</td>
<td>N/A</td>
<td>0.8mm +0.2/-0.0mm</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>GSB04-B</td>
<td>Straight</td>
<td>Φ6.4mm +0.0/-0.3mm</td>
<td>260mm±8mm</td>
<td>2.3mm +0.2/-0.0mm</td>
<td>1.1mm +0.2/-0.0mm</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>GSB14-B</td>
<td>Curved distal tip</td>
<td>Φ6.4mm +0.0/-0.3mm</td>
<td>260mm±8mm</td>
<td>2.3mm +0.2/-0.0mm</td>
<td>1.1mm +0.2/-0.0mm</td>
<td>22° ±5°</td>
<td>25mm ±1.3mm</td>
</tr>
</tbody>
</table>

The video processor provides power and processes the images from the Rigid Hysteroscopes. Anatomical images are collected via a CMOS chip at the distal end of the hysteroscope and are transmitted through the video processor to a monitor.

V. Indications for use

The Hysteroscope System is intended to be used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.

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

Generally recognized indications for diagnostic hysteroscopy include:

• Abnormal bleeding
• Infertility and pregnancy wastage
• Evaluation of abnormal hysterosalpingogram
• Intrauterine foreign body
• Amenorrhea
• Pelvic pain
Generally recognized indications for operative hysteroscopy include:

- Directed endometrial biopsy
- Polypectomy
- Submucous myomectomy
- Transection of intrauterine adhesions
- Transection of intrauterine septa
- Endometrial ablation

**VI. Comparison of technological characteristics with the predicate devices**

The Hysteroscope System has the same intended use as the predicate device. The Hysteroscope System and the predicate device are designed to provide real-time images to the physician in order to facilitate diagnostic and therapeutic procedures in the cervical canal and uterus. As summarized in the table below, there are differences in technological characteristics between the subject and predicate device. The technological differences between the Hysteroscope System and predicate device do not raise different questions of safety or effectiveness.

<table>
<thead>
<tr>
<th>Device Feature</th>
<th>Hysteroscope System (subject device)</th>
<th>LiNA OperaScope K171113</th>
<th>Discussion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for use</td>
<td>The Hysteroscope System is intended to be used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures. Note: Hysteroscopes are used as tools to access the uterine cavity and are not, in and of themselves, a method of surgery. Generally recognized indications for diagnostic hysteroscopy include: Abnormal bleeding</td>
<td>The LiNA OperaScope is intended for use in visualization of the cervical canal and uterine cavity during diagnostic and therapeutic gynecological procedures. The types of procedures where the OperaScope could offer visualization include: Assessment of abnormal bleeding, pelvic pain, amenorrhea and abnormal findings from hysterosalpingogram; Assessment of Infertility and pregnancy wastage; Confirmation of the presence of intrauterine foreign body; Assist in locating submucosal fibroids and polyps targeted for</td>
<td>Similar; the difference in wording of the indications does not alter the intended use.</td>
</tr>
<tr>
<td>System Components</td>
<td>The Hysteroscope System consists of a sterile single-use disposable Rigid Hysteroscope and video processor for clinical image processing.</td>
<td>Sterile/Single-use Handpiece (Hysteroscope) with CMOS camera, LED illumination, LCD display unit, channel for infusion of irrigating fluid, channel for fluid outflow, microelectronics, firmware and single use batteries for powering the device. Non-Sterile/Reusable Recording Module with software, microelectronics and controls for recording pictures/video, HDMI ports (2) for connection to</td>
<td>Similar; the basic system composition is identical (single use scope with video processor).</td>
</tr>
</tbody>
</table>

- Infertility and pregnancy wastage
- Evaluation of abnormal hysterosalpingogram
- Intrauterine foreign body
- Amenorrhea
- Pelvic pain
Generally recognized indications for operative hysteroscopy include:
- Directed endometrial biopsy
- Polypectomy
- Submucous myomectomy
- Transection of intrauterine adhesions
- Transection of intrauterine septa
- Endometrial ablation removal;
- Provide visual guidance during directed biopsy, submucosal myomectomy, transection of intrauterine adhesions and septa.
<table>
<thead>
<tr>
<th>Feature</th>
<th>Device A</th>
<th>Device B</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handpiece</td>
<td>Handpiece (hysteroscope) and external monitor and input port for external 9V DC power supply.</td>
<td>Handpiece (hysteroscope) and external monitor and input port for external 9V DC power supply.</td>
<td>Identical</td>
</tr>
<tr>
<td>Optical Image CMOS Technology</td>
<td>CMOS</td>
<td>Digital CMOS Technology</td>
<td>Identical</td>
</tr>
<tr>
<td>Image Resolution</td>
<td>100,000 pixels</td>
<td>CMOS camera consists of approximately 160,000 pixels</td>
<td>Different; the difference does not raise different questions of safety or effectiveness.</td>
</tr>
<tr>
<td>Illumination Light Source LED</td>
<td>LED</td>
<td>LED at tip of cannula</td>
<td>Identical</td>
</tr>
<tr>
<td>Inflow and outflow channel for saline instillation</td>
<td>Inflow and outflow channels separately</td>
<td>Inflow: Inflow channel and working channel combined in one channel above the camera. Outflow: One outflow channel with two entrances placed on top and bottom of distal tip.</td>
<td>Different; The difference does not raise different questions of safety or effectiveness.</td>
</tr>
<tr>
<td>Cannula tip design</td>
<td>Angled shaft proximal to tip: Straight: 0º Curved tip: 22º</td>
<td>Rounded polymer tip. Angled shaft proximal to tip (~ 20º). Steerable by rotation knob.</td>
<td>Different; the predicate device is steerable by rotation knob. The difference does not raise different questions of safety or effectiveness.</td>
</tr>
<tr>
<td>Image Transmission</td>
<td>Transmits images are transmitted to the user by the video processor with a CMOS chip at the distal end of the endoscope and the image showing on a monitor.</td>
<td>Transmits images from CMOS video camera to local LCD display unit on the handpiece and remote monitor.</td>
<td>Identical</td>
</tr>
<tr>
<td>Maximum</td>
<td>4.0 to 6.4 mm</td>
<td>4.3 mm</td>
<td>Different; the</td>
</tr>
</tbody>
</table>
**Insertion Diameter (Tip)**

<table>
<thead>
<tr>
<th>Diameter depending on model</th>
<th>difference in diameter does not raise different questions of safety or effectiveness.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shaft/Cannula Length</td>
<td>260mm 240mm (24cm)</td>
</tr>
<tr>
<td></td>
<td>Different; the difference in length does not raise different questions of safety and effectiveness.</td>
</tr>
</tbody>
</table>

**Energy Source**

<table>
<thead>
<tr>
<th>Energy Source</th>
<th>Similar; Different output formats do not raise different safety or effectiveness.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hysteroscope: 5V</td>
<td></td>
</tr>
<tr>
<td>Video Processor: 5V 2A</td>
<td></td>
</tr>
<tr>
<td>Handpiece: 3V (2 AA batteries)</td>
<td></td>
</tr>
<tr>
<td>Recording Module: 9V DC</td>
<td></td>
</tr>
<tr>
<td>external power adapter</td>
<td></td>
</tr>
</tbody>
</table>

**Sterilization**

<table>
<thead>
<tr>
<th>Sterilization</th>
<th>The Rigid Hysteroscope is provided sterilized by EO. No re-sterilization is permitted.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Video Processor: Non-Sterile</td>
<td></td>
</tr>
<tr>
<td>Handpiece (Hysteroscope): Ethylene Oxide (EO)</td>
<td></td>
</tr>
<tr>
<td>Handpiece Batteries: Radiation (Gamma)</td>
<td></td>
</tr>
<tr>
<td>Recording Module: Non-Sterile</td>
<td></td>
</tr>
</tbody>
</table>

**VII. Performance data**

The following performance data were provided in support of the substantial equivalence determination.

**Biocompatibility testing**

Biocompatibility of the Hysteroscope System was evaluated in accordance with ISO 10993-1:2009 for the body contact category of “Surface – Mucosal Membrane” with a contact duration of “Limited (< 24 hours)”. The following tests were performed:

- Cytotoxicity per ISO 10993-5:2009
- Irritation and Sensitization per ISO 10993-10:2010

The device was demonstrated to be non-cytotoxic, non-sensitizing and non-irritating.

**Sterilization and shelf life testing**

The ethylene oxide sterilization method has been validated to ISO 11135:2014. The shelf life of the Rigid Hysteroscope was demonstrated through a stability study which included...
testing of aged devices to ensure devices maintained specifications and that device packaging maintained sterility.

**Electrical safety and electromagnetic compatibility (EMC)**


**Software Verification and Validation Testing**

Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices for a “moderate” level of concern.

**Optical performance testing**

Optical performance testing was conducted on the Hysteroscope System. The optical performance of the system complies with ISO 8600 series. The system was demonstrated to meet predefined acceptance criteria.

**Mechanical performance testing**

Mechanical characteristics including leaking, bending, articulating and irrigation tests were performed. Devices were demonstrated to meet predefined acceptance criteria.

**VIII. Conclusion**

The subject device has the same intended use as the predicate, and differences in technological characteristics between the subject and predicate devices do not raise different questions of safety or effectiveness. The non-clinical testing demonstrates that the subject device is as safe and as effective as the legally marketed predicate device. Therefore, the subject device is substantially equivalent to the predicate.