DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 13, 2016

Lutech Industries, Inc.
% Jimmy Wu
Associate
Lee & Xiao
2600 Mission St, Ste. 100
San Marino, CA 91108

Re: K160380
Trade/Device Name: LT-300 HD
Regulation Number: 21 CFR 884.1630
Regulation Name: Colposcope
Regulatory Class: Class II
Product Code: HEX
Dated: February 11, 2016
Received: February 16, 2016

Dear Jimmy Wu,

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

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

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

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K160380

Device Name
LT-300 HD

Indications for Use *(Describe)*

The LT-300 HD digital video colposcope is intended for the magnified viewing of the vagina, cervix and external genitalia in order to aid in diagnosing abnormalities and select areas for biopsy. The image can be viewed on a color screen or computer monitor and printed on a color printer. The device is intended to be used in hospitals and clinics.

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.

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# 510(k) SUMMARY

## 1. Submitter

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Phone: 1-513-693-3697
Email: jwu@leexiao.com

Date Submitted: 2/5/2016

## 2. Device

| | |
|---|---|
| Device Name: | LT-300 HD |
| Common Name: | Colposcope (HEX) |
| CFR Section: | 21 CFR 884.1630 |
| Product Classification: | Class II |
| Classification Panel: | Obstetrics/Gynecology |
| Product Code: | HEX |

## 3. Predicate Device

LT-300 Digital Colposcope, K143119

## 4. Device Description:

LT-300 HD digital video colposcope is a digital video colposcope intended to provide magnified viewing of the vagina, cervix and external genitalia. LT-300 HD digital video colposcope is used to diagnose abnormalities and select areas for biopsy. LT-300 HD digital video colposcope acquires and displays high-resolution still and sequentially captured images and videos.

LT-300 HD digital video colposcope offers non-patient contact, fully digital and high-resolution imaging of the cervix. The field of view is illuminated by circular LED group light source; a high-resolution color CCD camera provides crisp magnified color images. The images can be viewed on a commercially available color monitor.

Components: Digital Camera, Vertical Stand, Remote Control

## 5. Intended Use

The LT-300 HD digital video colposcope is intended for the magnified viewing of the vagina, cervix and external genitalia in order to aid in diagnosing abnormalities and select areas for biopsy. The image can be viewed on a color screen or computer monitor and printed on a color printer. The device is intended to be used in hospitals and clinics.

## 6. Comparison of Technological Characteristics With The Predicate Device

Both subject and predicate devices use digital camera with accessories to provide magnified viewing of the vagina, cervix and external genitalia.

The subject and predicate devices are based on the following same technological elements:

- Digital Camera with magnification – both devices contain digital camera with Auto/Manual focus, and the digital cameras are used to view the target body organs;
- Vertical Stand – used to adjust the position of the digital camera;
- Light Source – loop group LED white light;
- Illuminance – both device's illuminances are ≥ 2000Lux at working distance 300 mm;
- Field of View – both devices' Field of Views are 52° or at minimum magnification ≥ Φ60mm & at maximum magnification ≥ Φ10mm;
- Depth of Field – both devices' Depth of Fields are: at minimum magnification ≥ 120mm; at maximum magnification ≥5mm;
- Performance Standards – both devices conform to same consensus standards.

The following technological differences exist between the subject and predicate devices:

- System Resolution
- Image Geometric Distortion
- Optical Magnification
- Electronic Filter
- Video Output
- Accessory – Remote Control

These differences do not raise different questions of safety or effectiveness, and accepted test methods were used to assess the effects of these differences on device performance.

## 7. Nonclinical Tests

LT-300 HD digital video colposcope meets following performance standards:

- ISO 8600-3:1997 Optics and optical instruments—Medical endoscopes and endoscopic accessories part 3: Determination of field of view and direction of view of endoscopes with optics.
- ISO 8600-5:2005 Optics and photonics-Medical endoscopes and endotherapy devices part 5: Determination of optical resolution of rigid endoscopes with optics
- IEC 60601-1:2005 Medical Electrical Equipment - Part 1 General requirements for safety and essential performance.
- IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests.

Other nonclinical tests on thermal safety, image quality and device reliability were met:

- Thermal Safety Test
- Image Distortion Test
- Field of View Test

## 8. Conclusion

The LT-300 HD digital video colposcope has the same intended use as the predicate device and the technological characteristics do not raise different questions of safety and effectiveness compared to the predicate device. The non-clinical testing, which included the use of recognized performance standards, demonstrates that the LT-300 HD digital video colposcope is substantially equivalent to the predicate device.