April 23, 2021

Liger Medical, LLC
Wm. Dean Wallace, MD, Ph.D.
President
3300 North Running Creek Way, Building G, Suite G20
Lehi, UT 84043

Re: K202915
Trade/Device Name: IRIS Thermocoagulator and Digital Colposcope
Regulation Number: 21 CFR§ 884.4120
Regulation Name: Gynecologic Electrocautery and Accessories
Regulatory Class: II
Product Code: HGI, PTZ
Dated: March 24, 2021
Received: March 26, 2021

Dear Wm. Dean Wallace:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jason R. Roberts, Ph.D.
Assistant 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202915

Device Name
IRIS Thermocoagulator and Digital Colposcope

Indications for Use *(Describe)*
The IRIS Thermocoagulator and Digital Colposcope is intended for the destruction of human tissue with high temperatures by tissue contact with an electrically heated probe, and to provide magnified visualization of the tissues of the vagina, cervix and external genitalia in order to aid in selecting areas for biopsy and diagnosing abnormalities as needed for a colposcopy exam.

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: K202915

1. **Submitter Information**

Manufacturer Name and Address
Liger Medical LLC
3300 North Running Creek Way
Building G, Basement Suite G20
Lehi, Utah 84043
USA
Phone: 801-256-6576

Official Correspondent
Wm. Dean Wallace MD, PhD
Liger Medical LLC
3300 North Running Creek Way
Building G, Basement Suite G20
Lehi, Utah 84043

2. **Date Prepared:** April 20, 2021
3. **Device Information:**

Proprietary Name: IRIS Thermocoagulator and Digital Colposcope

Common Name: Thermocoagulator and Colposcope

FDA Classification:

	Thermocoagulator	Colposcope
Product Code:	HGI	PTZ
Regulation Name:	Gynecologic Electrocautery and Accessories	Colposcope, Exempt
Regulation Number:	21 CFR 884.4120	21 CFR 884.1630
Regulatory Class:	Class II	Class II

4. **Predicate Device(s):**

The IRIS Thermocoagulator & Digital Colposcope is substantially equivalent to the following device(s):

Manufacturer	Device	510(k)	Date Cleared
Liger Medical LLC	Liger Medical Thermocoagulator HTU-110	K152843	06/24/2016

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MobileODT Ltd.	EVA (Enhanced Visual Assessment) System	K161871	12/19/2016

The predicate devices have not been subject to a design-related recall.

5. Device Description

The Liger Medical IRIS Thermocoagulator and Digital Colposcope is a portable thermal coagulator with integral colposcope that provides assistance for clinician examination of the cervix as well as utilizes a heated probe to ablate human tissue. It is specifically designed for use in resource-limited settings. The colposcope and thermal ablation modes can be used separately from each other. The device is a handheld, portable, battery-operated, ablator with an LCD display and optical camera to assist diagnosis and treatment, in a safe, effective, easy to use package with sufficient battery life to sustain work for 4 hours. Thermal coagulation or tissue ablation can be used in hospital and non-hospital professional healthcare locations.

The IRIS colposcope/thermal ablation device is not intended for introduction into the vaginal canal during colposcopic examination. The camera remains outside the vaginal cavity and functions comparably to a standard non-invasive colposcope in terms of providing magnified visual assistance to the clinician. There is no patient contact during the colposcopic examination. Contact between the clinician and the device is mitigated through good clinical practice of wearing protective gloves, limiting contact to intact skin protected by operating gloves.

The thermal ablation probe, which is reusable and provided non-sterile, is designed to perform low-power destruction of human tissue with high temperatures by tissue contact with an electrically heated probe tip. The biocompatibility of the probe materials conforms to all recommended endpoints per FDA's guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" for limited duration mucosal membrane contact.

ACCESSORIES

The IRIS is compatible with the following accessories:

- Liger Medical HTU-110 Thermocoagulator 19mm Flat Probe
- Liger Medical HTU-110 Thermocoagulator 19mm Nipple Probe
- Liger Medical HTU-110 Thermocoagulator 16mm Flat Probe

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6. Indications for Use

The IRIS Thermocoagulator and Digital Colposcope is intended for the destruction of human tissue with high temperatures by tissue contact with an electrically heated probe, and to provide magnified visualization of the tissues of the vagina, cervix and external genitalia in order to aid in selecting areas for biopsy and diagnosing abnormalities as needed for a colposcopy exam.

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7. Predicate Comparison

The following table compares the IRIS Thermocoagulator & Digital Colposcope to the predicate device(s) with respect to indications for use, technological characteristics, and materials:

Product Attribute	Primary Predicate Device: Liger Medical HTU-110 (K152843)	Subject Device: Liger Medical IRIS Thermocoagulator and Digital Colposcope (K202915)	Secondary Predicate Device: MobileODT EVA (K161871)
Indications for Use:	Intended for the destruction of human tissue with high temperatures by tissue contact with an electrically heated probe	The IRIS Thermocoagulator and Digital Colposcope is intended for the destruction of human tissue with high temperatures by tissue contact with an electrically heated probe, and to provide magnified visualization of the tissues of the vagina, cervix and external genitalia in order to aid in selecting areas for biopsy and	The EVA (Enhanced Visual Assessment) System is intended to provide magnified viewing of the vagina, cervix and external genitalia in order to aid in diagnosing abnormalities and selecting areas for biopsy. The device is intended for use in hospitals, doctor's offices, and remote and rural clinics.

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		diagnosing abnormalities as needed for a colposcopy exam.	
Product Classification:	Gynecologic electrocautery and accessories (21 CFR 884-4120) Product code: HGI Class II	Gynecologic electrocautery and accessories (21 CFR 884.4120) Product Code: HGI Colposcope, Exempt (21 CFR 884.1630) Product Code: PTZ Class II	Colposcope (21 CFR 884.1630) Product Code: HEX Class II
Where Used:	Professional Healthcare Environment	Same	Professional Healthcare Environment
Energy Used:	12V Lithium-ion battery	Same	Unknown
Maximum Output Power:	49W	Same	Not Applicable
Method of Activation:	On/Off Switch	Same	On/Off Switch
Thermal Ablation Temperature Set Point	100°C	100 – 120°C	Not Applicable
Thermal Ablation Duty Cycle	45 seconds	20 – 60 seconds	Not Applicable
Method of Operation:	Single-button with Status LEDs	Touchscreen with Status LEDs	Touchscreen with Status LEDs
Materials:	Polycarbonate	Same	Unknown
Biocompatibility:	ISO 10993-1:2009 Validated	Same	Not Applicable
Method of Visualization	LED Illumination with Direct Observation with Unaided Eye	LED Illumination with Direct Observation with Unaided Eye	LED Illumination with Direct Observation with Unaided Eye

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		and/or Camera Assisted visualization with Display	and/or Camera Assisted visualization with Display
Working Distance	Not Applicable	100-400mm	225-425mm
Focusing Mechanism	Not Applicable	Manual	Manual
Magnification	Not Applicable	18x	225: 16x 425: 15x
Digital Magnification	Not Applicable	1x-4x	1x-4x
Optical magnification	Not Applicable	3x	225: 4.0x 425: 3.8x
Depth of Field	Not Applicable	15mm (at 200mm) - 35mm (at 450mm)	17mm (at 225mm) - 34mm (At 425mm)
Field of View	Not Applicable	55mm (at 200mm) - 123mm (at 450mm)	45mm (at 225mm) - 100mm (at 425mm)
On-axis Spatial Resolution	Not Applicable	15.75 lp/mm	11.78 lp/mm
On-axis Angular Resolution	Not Applicable	0.029 deg	0.022 deg
Distortion	Not Applicable	<3.0%	<2.5%
Light Source	Not Applicable	2W 5000K LED	3W 6500K star LED
Color	Not Applicable	Digital green filter, polarizing/glare reducing filter	Digital green filter, polarizing/glare reducing filter
Image Output	Not Applicable	Image capture, cloud image exporting	Image capture, cloud patient recording and image exporting
Image Freeze	Not Applicable	Full image capturing support	Full image capturing support
Illuminance	Not Applicable	7200lux at 300mm	>1000lux at 425mm

LIGER MEDICAL
Innovation for Better Women's Health

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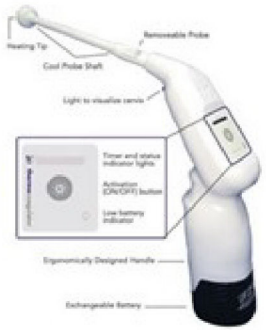
Pictures			

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review. The IRIS Thermocoagulator & Digital Colposcope has the same intended use but different technological characteristics compared to the predicate device(s). The differences in technological characteristics do not raise different questions of safety and effectiveness and can be evaluated through performance testing.

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8. Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the IRIS Thermocoagulator & Digital Colposcope met all design input requirements and is substantially equivalent to the predicate device(s).

The IRIS Thermocoagulator & Digital Colposcope was tested for electrical/mechanical/thermal safety and EMC according to the following standards:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
- IEC 60601-1-2:2014 (4th Ed)

The following additional bench testing for performance verification and validation purposes was performed:

- Probe Fault Detection
- Battery Fault Detection
- Probe Heat-up time and Temperature Stability at Set-Point
- Heater Circuit Hardware Checks
- Heater Performance on Tissue
- Software Application Testing
- Use-Life Testing
- Interoperability and Connectivity Testing
- Endoscope General Requirements per ISO 8600-1:2015
- Field of View and Direction of View per ISO 8600-3:2019
- Limiting Spatial Resolution

9. Clinical Performance Data

Not Applicable

10. Conclusion

Based on the comparison and analysis above, the IRIS Thermocoagulator & Digital Colposcope is substantially equivalent to the predicate device(s).