February 24, 2023

Elidah, Inc.
Gloria Kolb
CEO
810 Main St., Suite C
Monroe, CT 06468

Re: K223884
Trade/Device Name: ELITONE Urge Urinary Incontinence Device
Regulation Number: 21 CFR§ 876.5330
Regulation Name: Transcutaneous Electrical Continence Device
Regulatory Class: II
Product Code: QAJ
Dated: December 27, 2022
Received: December 27, 2022

Dear Gloria Kolb:

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,

Negeen Haghighi -S

for
Jessica K. Nguyen, 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)*
K223884

Device Name

ELITONE Urge Urinary Incontinence Device

Indications for Use *(Describe)*

ELITONE Urge is a non-implanted muscle stimulator designed to treat urge urinary incontinence in women. It applies stimulation to the pelvic floor muscles and surrounding tissues.

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

Sponsor: Elidah, Inc.
810 Main St, Suite C.
Monroe, CT 06468
Contact: Gloria Kolb
Phone: 978-435-4324
Date Prepared: 2/20/23

Device Information: Trade Name: ELITONE Urge Urinary Incontinence Device
Common Name: Non-implanted electrical continence device
Classification Name: Transcutaneous electrical continence device
Classification Product Code: QAJ
Regulation Number: 876.5330
Device Classification: Class II

Predicate Device: ELITONE (K183585), manufactured by Elidah, Inc.
The predicate device has not been subject to a design-related recall.

Device Description:

The ELITONE Urge Urinary Incontinence Device (hereafter ELITONE URGE or ELITONE UUI) provides electrical muscle stimulation (commonly called EMS or E-stim) to treat urge urinary incontinence. Stimulation is delivered to the pelvic floor muscles and surrounding structures through a disposable cutaneous electrode applied to the perineal region. One end of the thin, flexible electrode is positioned proximate the pubis and the other end is positioned proximate the ischial tuberosity. Mildly adhesive and electrically conductive hydrogel portions of each electrode attach the electrode to the perineal tissues and allow comfortable transfer of electrical stimulation through the pelvic floor. The stimulation is controlled by a battery powered, wearable control unit. The housing of the control unit is approximately 55mm x 45mm x 10mm. It includes two pushbuttons that allow the user to increment or decrement the voltage (i.e., intensity), and to start, pause and stop device operation. The stimulation utilizes a symmetric, amplitude-modulated, sinusoidal waveform. The output intensity operates over a range of levels (0-35) that approximately correspond to a 0-15mA RMS current. The stimulation frequency is 10 Hz, a frequency typically used to calm detrusor muscle activity, decreasing symptoms of urgency type incontinence. Each treatment session lasts 20 minutes, after which the device turns off automatically. Women are recommended to use the device 4-5 times per week.

Intended Use:
ELITONE URGE is a non-implanted muscle stimulator designed to treat urge urinary incontinence in women. It applies stimulation to the pelvic floor muscles and surrounding tissues.

Comparison to the Predicate Device:
The table below provides comparisons of the proposed ELITONE UUI device to the predicate ELITONE device (hereafter ELITONE SUI for clarity). The difference between ELITONE UUI and the predicate is the

composition of the output signal. Each stimulation cycle of the predicate's output combines a 50Hz signal (understood to treat stress urinary incontinence) and a 10Hz signal (understood to treat urge urinary incontinence), whereas the proposed ELITONE UUI output is solely 10Hz. This difference is achieved through a modification to the embedded software. Product labeling has been changed to reflect the new Indication for Use. All other elements of the two products are identical. Differences in technological characteristics do not raise different questions of safety and effectiveness.

Technological Characteristic	ELITONE UUI Device (New Device)	ELITONE SUI Device (K183585)	Comparison and Impact on Safety/Performance
Indication for Use	non-implanted muscle stimulator designed to treat urge urinary incontinence in women. It applies stimulation to the pelvic floor muscles and surrounding tissues.	non-implanted muscle stimulator designed to treat stress urinary incontinence in women. It applies stimulation to the pelvic floor muscles and surrounding tissues.	Substantially Equivalent. Both have an intended use for the treatment of urinary incontinence in women.
Therapeutic modality	Electrical muscle stimulation	Electrical muscle stimulation	Identical
Rx or OTX	Rx and OTC	Rx and OTC	Identical
Targeted tissue	Pelvic floor muscles and surrounding structures	Pelvic floor muscles and surrounding structures	Identical
Anatomic site of stimulation application	Perineal region	Perineal region	Identical
Device Materials	Controller Housing - ABS Electrode – Polyethylene, Hydrogel, PET	Controller Housing – ABS Electrode – Polyethylene, Hydrogel, PET	Identical
Sterility Status	Non-sterile	Non-sterile	Identical
Shelf-Life	2-Year shelf life on GelPads	2-Year shelf life on GelPads	Identical
Number of output modes	1	1	Identical
Number of output channels	1	1	Identical
Controls	2 buttons provide all functionality	2 buttons provide all functionality	Identical
Compliance with voluntary standards	IEC 60601-1 IEC 60601-2-10 IEC 60606-1-2	IEC 60601-1 IEC 60601-2-10 IEC 60606-1-2	Identical
Waveform	Modulated, symmetric (250µs/phase).	Modulated, symmetric (250µs/phase).	Identical
Stimulation Frequency	10 Hz Amplitude modulated at 2000Hz	50 Hz,10 Hz Amplitude modulated at 2000Hz	Substantially equivalent: Both utilize frequencies known to treat UUI (10-15 Hz).
Time (Cycle Duration?)	6s at 10 Hz 6s no stimulation	4s at 50 Hz 2s at 10 Hz 6s no stimulation	Substantially equivalent: Both utilize contract/relax sequencing consistent with known treatments for incontinence.
Max output voltage (500Ω)	Vrms = 8V Vpp = 43V	Vrms = 15V at 50Hz, 8V at 10Hz Vpp = 43V	Identical to 10Hz portion of predicate

Technological Characteristic	ELITONE UUI Device (New Device)	ELITONE SUI Device (K183585)	Comparison and Impact on Safety/Performance
Max output current (500Ω)	I_{pp} – 97mA I_{rms} –11.4mA	I_{pp} – 97mA I_{rms} –28.2mA at 50Hz, 11.4mA at 10 Hz	Identical to 10Hz portion of predicate
Max current density	RMS: 0.4 mA/cm^2 Peak: 3.5 mA/cm^2	RMS: 1.0 mA/cm^2 at 50Hz, 0.4mA/cm^2 at 10Hz Peak: 3.5 mA/cm^2	Identical to 10Hz portion of predicate
Maximum Power Density (W/cm$^{2)}$	0.0032 W/cm^2	0.015 W/cm^2 at 50Hz, 0.0032 W/cm^2 at 10Hz	Identical to 10Hz portion of predicate
Maximum Phase Charge (µC @ 500Ohms)	9.09 µC	9.09 µC	Identical

Testing Summary:
The following performance testing was provided in support a substantial equivalence determination.

- Software Verification and Validation Testing - The software for the device was considered to be a "moderate" level of concern. Verification and validation testing was conducted in accordance with the FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005.
- Electrical Safety and Electromagnetic Compatibility (EMC) Testing – Testing was completed by external labs per IEC 60601-1 and IEC 60601-2-10 standards for safety and IEC 60601-1-2 standard for EMC.
- Other Performance Testing – Performance of the electrode component was assessed by measuring its impedance, its adhesiveness and its current dispersion. Comparisons were made to legally marketed EMS electrodes.
- Biocompatibility Assessment – A biocompatibility evaluation was completed in accordance with the ISO 10993-1 standard. The electrode is considered tissue contacting for a duration of less than 24 hours. The materials, manufacturing processes and use application are the same as those of legally marketed electrodes. Accordingly, no new biocompatibility testing was needed to demonstrate safety and efficacy.
- Clinical Literature Evaluation – A literature review was conducted to demonstrate the safety and efficacy of perineal-applied EMS in the treatment of female urinary incontinence. Articles were reviewed to assess their relevance to the performance and safety of the device.
- Clinical Testing – Clinical testing was conducted on women with urge urinary incontinence in the US. The study design was a single-arm study with the patient serving as own control (i.e., comparison to baseline). Subjects self-administered treatment for 6-weeks. The pre-specified primary efficacy endpoint was the percent change in urge leaks per day, determined by comparing 7-day baseline data with data from the 6th week of treatment. Responders were defined as achieving ≥50% reduction in urge leaks. Pre-specified secondary efficacy endpoints included: changes in urgency episodes (i.e., combined number of urge leaks and urgency events that did not result in a leak) with responders defined as achieving ≥50% reduction, changes in pad use with responders defined as achieving ≥50% reduction, and changes in I-QoL score with responders defined as achieving ≥2.5 points change. Subjects with urge incontinence symptoms predominant to stress incontinence symptoms (if present) were randomly assigned to treat with one of two

devices, one of which was the subject ELITONE UUI device. 15 subjects were included in analysis of the ELITONE UUI device. Clinical testing was later expanded (under a second IRB-approved protocol) to include a cohort of women with urge urinary incontinence without stress incontinence symptoms. These subjects self-administered treatment for 6-weeks with the ELITONE UUI device according to the same protocol as the first cohort. Pre-specified primary and secondary endpoints aligned with those from the first cohort of subjects. 19 subjects were included in the analysis of this second cohort. The protocol detailing the expanded data collection specifies intent to pool data from the two testing periods. Accordingly, 34 subjects were included in the final analysis. For the primary efficacy endpoint, 76% of participants responded to the treatment. Responder rates for the secondary endpoints were: 76% for urgency episodes, 91% for I-QoL, and 32% for pad use. The primary safety endpoint was defined as adverse events that resulted in an injury or required medical treatment. None were reported. The self-administered, at home treatment limited the opportunity for direct oversight by study personnel, making it relatively easy for subjects to enroll and then subsequently opt-out of participation before initiating treatment. In the first cohort, 26 subjects were shipped the ELITONE UUI device (i.e., enrollment), 15 returned the study device demonstrating at least one treatment session (i.e., treatment), and 15 were found to have completed the study protocol (i.e., analysis). Enrollment, treatment, and analysis values for the second cohort were 30, 23, and 19 respectively.

Risk Management Summary:
ELITONE UUI has been designed according to Elidah's internal procedures with traceability between the design inputs, design outputs, verification and validation activities. ELITONE UUI has been evaluated for risks according to Elidah's internal procedures based on ISO 14971. The risks associated with ELITONE UUI were individually and collectively assessed, and the risk/benefit analysis was acceptable.

Conclusion:
The non-clinical data demonstrate that ELITONE UUI is as safe as the predicate. The software verification and validation demonstrate that ELITONE UUI performs as intended in the specified use conditions. The clinical literature evaluation supports the use of transcutaneous electrical stimulation as an effective treatment of urge urinary incontinence in women. The clinical study data demonstrates that ELITONE UUI is as safe and effective as the predicate device. Collectively, performance testing supports a Substantial Equivalence determination.