January 23, 2026

Elidah, Inc.
Gloria Kolb
CEO
31 Pecks Ln
Suite 11
Newtown, Connecticut 06470

Re: K253285
Trade/Device Name: Elitone for Men
Regulation Number: 21 CFR 876.5330
Regulation Name: Transcutaneous electrical continence device
Regulatory Class: II
Product Code: QAJ
Received: December 23, 2025

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 (the 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 available 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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JESSICA K. NGUYEN -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253285

Please provide the device trade name(s).

Elitone for Men

Please provide your Indications for Use below.

Elitone for Men is a non-implanted muscle stimulator designed to aid early continence recovery in men immediately following prostate surgery.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K253285

510(k) Summary

Prepared on: 2026-01-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Elidah, Inc.
Applicant Address	31 Pecks Ln Suite 11, Newtown CT 06470 United States
Applicant Contact Telephone	978-435-4324
Applicant Contact	Mrs. Gloria Kolb
Applicant Contact Email	gloria@elidah.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Elitone for Men
Common Name	Transcutaneous Electrical Continence Device
Classification Name	Cutaneous Electrode Stimulator For Urinary Incontinence
Regulation Number	876.5330
Product Code(s)	QAJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K183585	Elitone	QAJ

Device Description Summary

21 CFR 807.92(a)(4)

The Elitone for Men device is an electrical muscle stimulator designed to speed continence recovery in men following prostate surgery. Stimulation is delivered to the pelvic floor muscles and surrounding structures via a disposable electrode component configured to be applied to the skin in the perineal region. A small control unit component generates a therapeutic stimulation and allows the patient to increment or decrement the stimulation intensity. The applied electrical stimulation causes muscle contraction and relaxation in a treatment regimen that, with regular use over multiple weeks, is intended to speed continence recovery.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Elitone for Men is a non-implanted muscle stimulator designed to aid early continence recovery in men immediately following prostate surgery.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indication for use is specific to use by males following prostate surgery, whereas the predicate is specific to females. This is a necessary distinction because the patient-contacting component is anatomically shaped to fit the male anatomy. The intended use is unchanged, as both the subject and predicate devices deliver electrical muscle stimulation through a perineal-applied electrode to treat urinary incontinence.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device has the same technological characteristics as the predicate. Further, the Elitone for Men and Elitone devices are identical (i.e. shared components) except for the electrode component, which have profiles corresponding the male and female anatomy respectively. The materials, construction, and performance parameters of the electrodes are identical.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The FDA guidance document titled "Guidance Document for Powered Muscle Stimulator 510(k)s" was used in determining what types of bench tests were applicable for the controller component. Specifically, the table titled "Output Specifications" served as the template for characterizing performance. The subject Elitone for Men device shares components with the predicate Elitone device. Accordingly, no new bench testing was performed on the controller component. Performance of the electrode component, including for example the maximum current density, was characterized and found to be substantially equivalent to the predicate female electrode.

Clinical data were submitted to support the determination of substantial equivalence. The study was designed as a prospective case series. Sixteen subjects completed the treatment and were included in the analysis. Subjects initiated treatment with the Elitone for Men device approximately 1 month after prostate surgery (mean 35.5 ± 13.3 days post-surgery). The study population had a mean age of 65.3 ± 5.3 years and mean BMI of 27.5 ± 4.9. Subjects were treated 4-5 times per week for 12 weeks. Subjects recorded baseline incontinence symptoms prior to initiating treatment and maintained treatment/symptom logs throughout the study. Effectiveness was assessed by reduction in 24-hour pad weights.

A control group was needed given the significant natural recovery of continence that occurs following prostatectomy, particularly during the first-year post-surgery. A systematic literature review was conducted to establish a historical control cohort. Studies included in the analysis contained: quantitative continence outcomes reported using a 24-hour pad weight test; multiple continence assessments within the first three months following radical prostatectomy; and inclusion of a control cohort consisting of either no active treatment or self-guided pelvic floor muscle exercises. Studies were excluded if they did not include multiple early post-operative assessments or included physician-guided or supervised pelvic floor muscle exercise programs. The control cohort was comprised of a total of 215 subjects. The literature review population was comparable to the study population in terms of post-operative timing, with assessments beginning in the early post-prostatectomy period when natural recovery is most pronounced.

For the Elitone for Men study cohort, mean 24-hour pad weight was 608 ± 598 grams at baseline (n=15), decreased to 238 ± 315 grams at 6 weeks, and further decreased to 47 ± 65 grams at 12 weeks. Men treated with the Elitone for Men device had a mean reduction in 24-hour pad weight at 6 weeks of 61% compared to a 45% reduction in pad weight for the control cohort. At 12 weeks men treated with the device had a mean reduction in 24-hour pad weight of 92% compared to 68% for men in the control group. While the use of a historical control has inherent limitations including study heterogeneity, different patient populations, and varying surgical techniques across the referenced control studies, it provides evidence that the device may offer benefits beyond natural recovery.

No adverse events were reported during the study. Given the low-risk nature of this non-implanted, externally applied device, the observational clinical evidence provides acceptable support for safety and effectiveness in aiding early continence recovery in men immediately following prostate surgery.