March 20, 2026

LiviWell Inc.
% Chris Staab
Regulatory Consultant
Regulatory and Technical Associates
Contact Address

Re: K252005
Trade/Device Name: Livi Device
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: II
Product Code: HEB
Dated: June 27, 2025
Received: June 27, 2025

Dear Chris Staab:

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: 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.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

JASON ROBERTS -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252005

Device Name
Livi Device

Indications for Use *(Describe)*
The Livi device is intended for insertion into the vagina following sexual intercourse for the absorption of semen or other vaginal discharge. The device does not prevent pregnancy or protect against sexually transmitted infections (STIs).

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.

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510(k) SUMMARY

I. SUBMITTER

510(k) Holder: LiviWell Inc.
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Contact Person: Chris Staab
Regulatory Consultant
Regulatory and Technical Associates
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Date Prepared: March 20, 2026

II. DEVICES

Names of Devices: Livi Device
Regulation Name: Unscented Menstrual Tampon
Regulatory Class: Class II
Product Codes: HEB – Unscented Tampon

III. PREDICATE DEVICE

K241064 – Shandong Intco Hygiene Products Co., LTD. Unscented Tampon
The predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Livi device is an over the counter (OTC), single-use, non-sterile fluid absorptive device designed for insertion into the vagina for the absorption of semen or other vaginal discharge. The Livi device is intended to be worn for up to 15 minutes, and is not intended as a contraceptive, proceptive, or for use to absorb menstrual fluid during menstruation.

V. INDICATIONS FOR USE

The Livi device is intended for insertion into the vagina following sexual intercourse for the absorption of semen or other vaginal discharge. The device does not prevent pregnancy or protect against sexually transmitted infections (STIs).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

In accordance with the *510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* issued July 28, 2014, the comparison between the predicate device and the subject device is shown to be substantially equivalent by comparing the indications for use, principles of operation, technological characteristics, and performance testing similarities and differences (Table 1). The technological characteristic differences do not raise different questions of safety and effectiveness than the predicate device.

Table 1. Substantial Equivalence Subject Device Livi Compared to the Predicate Device Unscented Tampon

	K252005 LiviWell Inc. Livi Device		**K241064 SHANDONG INTCO HYGIENE PRODUCTS CO., LTD. Unscented Tampon**	
Product Code and Regulation Number	**HEB (21 CFR 884.5470)**		**HEB (21 CFR 884.5470)**	
Classification	II		II	
Indications for Use	The Livi device is intended for insertion into the vagina following sexual intercourse for the absorption of semen or other vaginal discharge. The device does not prevent pregnancy or protect against sexually transmitted infections (STIs).		The Unscented Tampon is intended for insertion into the vagina for the absorption of menstrual or other vaginal discharge.	
Single Use	Yes		Yes	
Sterility	No		No	
Design features	Livi is flower (tulip) shaped, with 3 petals Assembled device with smooth, rounded tip.		Tampon with cylindrical shape and bullet-like tip. Applicator with smooth, rounded tip.	
Component Materials	Livi	Polyurethane foam	Pledglet	Cotton / Viscose
	Removal String	100% cotton / polyester	Removal String	100% Cotton / Polyester and cotton
	Applicator	Polyethylene (PE)	Applicator	Cardboard
Packaging Materials	Overwrap	Multi-layer laminate including: Outer wrapper: Polyethylene terephthalate (PET)	Overwrap	Polyethylene and Polyethylene terephthalate (PET)

		Middle layer: Aluminum Inner wrapper: Cast Polypropylene (CPP)		
Absorbency	Light (<6g*)		Light: ≤6g , Regular: 6~9g , Super: 9~12g, and Super Plus: 12~15g	
Product Dimensions	Foam length 74-78mm Foam diameter 18-22mm Removal string length 198-202mm Applicator length 90-94mm Applicator diameter 19-22mm		(For Light Absorbency Tampon): Pledget length 45 – 50 mm Pledget diameter 12.2–13.7 mm Removal string length 115 -175 mm Applicator length 120–125 mm Applicator diameter 13.8–14.2 mm	

***Note:** There is only one Livi device; an absorbency range for each device is not applicable to this device as it is not intended for use to absorb menstrual fluid.

VII. Summary of Non-Clinical Testing

Non-clinical testing was conducted to verify that the subject devices meet all design and performance specifications similarly to the predicate device. The following tests were conducted:

Biocompatibility

- Biocompatibility studies were performed on the Livi device in accordance with the FDA guidance document "Guidance for Industry and Food and Drug Administration Staff - Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process' issued on September 4, 2020 as follows:
  - In vitro cytotoxicity test per ISO 10993-5:2009
  - Skin sensitization test per ISO 10993-10:2021
  - Vaginal irritation test per ISO 10993-23:2021
  - Acute systemic toxicity test per ISO 10993-11:2017 (foam only)
- All the above tests were performed on the applicator and plunger, except acute systemic toxicity. The results demonstrated that the subject device is non-cytotoxic, non-irritating, non-sensitizing, and non-systemically toxic.

Bench Performance Testing

- The following performance characteristics were assessed on the Livi in accordance with the FDA guidance document "Guidance for Industry and FDA Staff - Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s)" issued on July 27, 2005.
  - Dimensional verification
  - String pull strength
  - Absorbency per Syngyna Testing (21 CFR 801.430)
  - Applicator expulsion force
  - Foam (device) integrity
  - Fiber/material shedding

- Preclinical Microbiology
  - Bioburden
  - Effect on vaginal microflora
  - S. aureus growth
  - TSST-1 production

- The results demonstrated that the subject device performs as intended, maintains integrity, and that the Livi device does not enhance the growth of any microbes tested and yields less TSST-1 when compared to a legally marketed tampon.

VIII. Clinical Tests

Acute vaginal mucosal safety

- A clinical investigation to evaluate the acute vaginal mucosal safety of repetitive, consecutive use of the Livi post-coital absorptive device under controlled in-clinic conditions, enrolling 60 participants who completed 180 observed device-use cycles with digital colposcopic examinations and structured follow-up was conducted. No Grade ≥2 mucosal trauma, device fragmentation, retained material, infections, allergic reactions, or unanticipated adverse events were observed. 6.7%, (12/180) were noted to have transient Grade 1 mucosal findings. Subject-reported symptoms included mild to moderate pain or discomfort (32/180 or 17.8%) with insertion but were self-limited, and both 24-hour follow-up and 7-day surveillance identified no serious adverse events or fragmentation. Overall, the clinical study confirmed device integrity and acceptable mucosal safety with repetitive consecutive use representative of the device's intended use under the conditions evaluated.

Self-selection and labeling comprehension study

- A self-selection and labeling comprehension study was conducted to evaluate whether both intended and non-intended users clearly understood the product's intended use and associated safety information. A total of 50 participants (25 intended users and 25 non-intended users) completed the study, which demonstrated that participants consistently understood the product's purpose, accurately identified whether they were appropriate users, and comprehended the labeling as presented. The results exceeded the predefined ≥85% success criteria for self-selection and all comprehension endpoints, supporting the conclusion that the labeling effectively communicates critical information for the intended and non-intended user population.

IX. CONCLUSIONS

The Livi device has similar technological characteristics to the predicate device (K241064), including intravaginal placement and absorbent material composition. While the predicate is intended for menstrual use, the Livi device is intended for post-coital absorption of semen or vaginal discharge and is explicitly not intended for contraceptive, proceptive, or menstrual use. These differences in intended use do not raise new

questions of safety and effectiveness, as the associated risks, including potential misuse as a tampon or misunderstanding of product purpose, are adequately mitigated through labeling and demonstrated user comprehension. Based on the totality of the evidence, including clinical and non-clinical performance data, the Livi device is as safe and as effective as the predicate device.