June 4, 2025

SK Zen LLC
% Juan Tezak
Consultant
Compliance 4 Devices
118 W Prive Cr.
Delray Beach, Florida 33445

Re: K242712
Trade/Device Name: LubriZenzs
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Received: May 5, 2025

Dear Juan Tezak:

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 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,

Monica D. Garcia -S

Monica D. Garcia, 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)*
K242712

Device Name
LubriZenzs

Indications for Use *(Describe)*
LubriZenzs is a personal lubricant for vaginal and/or penile application, intended to moisturize and lubricate to enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication. This lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary (K242712)

**I) SUBMITTER**


| | |
|---|---|
| Company Name: | SK Zen LLC |
| Address: | 1264 Bayview Cir, Weston |
| City, State, ZIP: | Florida, USA, 333326 |
| Telephone: | +1 (754) 262-7352 |
| Email: | Skzen.llc@gmail.com |
| Contact Person: | Sofía Carolina Herrera Mendoza |
| Date Prepared: | June 2, 2025 |


**II) Device**

| | |
|---|---|
| Device Trade Name: | LubriZenzs |
| Common Name: | Personal Lubricant |
| Regulation Name: | Condom |
| Regulation Number: | 21 CFR 884.5300 |
| Regulatory Class: | II |
| Product Code: | NUC (lubricant, personal) |

**III) Predicate Device**

| | |
|---|---|
| Predicate Manufacturer: | Trigg Laboratories DBA Wet International |
| Predicate Trade Name: | Wet Organics Personal Lubricant |
| Predicate 510(k): | K182027 |

The predicate device has not been subject to a design-related recall.

**IV) Device Description**

LubriZenzs is a non-sterile, water-based, over-the-counter personal lubricant that is compatible with natural rubber latex and polyisoprene condoms. Its formulation consists of water, propanediol, cellulose gum, algin, 1,2-hexanediol, sodium hyaluronate, lactic acid, gluconolactone, *Tremella fuciformis* (mushroom) extract, caprylhydroxamic acid, sodium benzoate, calcium gluconate, sodium hydroxide, xylitylglucoside, anhydroxylitol, glycogen, xylitol, and glucose.

The Lubricant comes in a 100 mL white polypropylene plastic airless pump bottle, with a clear overcap.

The lubricant has a shelf-life of 2 years.

Specifications

Device specifications for the LubriZenzs are listed in Table 1 below:

Table 1. Device Specifications for LubriZenzs

| Parameter | Test Method | Specification |
|---|---|---|
| Appearance | Visual Inspection | Appearance Clear, flowable |
| Color | Visual Inspection | Colorless |
| Odor | Olfactory Inspection | Odorless |
| pH | USP <791> | 4.5-5.0 |
| Viscosity | USP <912> | 10,000 – 25,000 cps |
| Osmolality | USP <785> | 135 - 380 mOsm/kg (1:10 dilution) |
| Total Microbial Count (TAMC) | USP <61> | < 100 cfu/g |
| Fungal/Yeast/ Mold Limits (TYMC) | USP <61> | < 10 cfu/g |
| Absence of Pathogenic Organisms (*Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella, Escherichia coli, Candida albicans*) | USP <62> | Absent |
| Antimicrobial Effectiveness | USP<51> | Meets USP <51> criteria for category 2. Bacteria: No less than 2.0 log reduction from initial count at 14 days, and no increase from the 14-day count at 28 days. Yeast and Molds: No increase from the initial calculated count at 14 days and 28 days. |

## V) Indication For Use

LubriZenzs is a personal lubricant for vaginal and/or penile application, intended to moisturize and lubricate to enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication. This lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

## VI) Comparison of Technological Characteristics

| | Subject Devices (K242712) | Predicate Device (K182027) |
|---|---|---|
| Indications for Use | LubriZenzs is a personal lubricant for vaginal and/or penile application, intended to moisturize and lubricate to enhance the ease and comfort of intimate sexual activity, and supplement the body's natural lubrication. This lubricant is | The Wet Organics Personal Lubricant is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural |

| | | |
|---|---|---|
| | compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms | lubrication. The product is compatible with natural rubber latex and Polyisoprene condoms. This product is not compatible with Polyurethane condoms. |
| Rx/OTC | OTC | OTC |
| Water-based | Yes | Yes |
| Ingredients | Water<br>Propanediol<br>Cellulose Gum<br>Algin<br>1,2- hexanediol<br>Sodium Hyaluronate<br>Lactic Acid<br>Gluconolactone<br>*Tremella fuciformis* (mushroom) extract<br>Caprylhydroxamic Acid<br>Sodium Benzoate<br>Calcium Gluconate<br>Sodium Hydroxide<br>Xylitylglucoside<br>Anhydroxylitol<br>Glycogen<br>Xylitol<br>Glucose | Purified Water<br>Organic aloe barbadensis leaf juice<br>Zemea Select Propanediol<br>Vegeluron Gel<br>Cellosize QP-30000-H<br>Xanthan Gum<br>Sodium Hyaluronate<br>Microcare SB<br>Citric Acid<br>Co Extract Blend |
| Sterile | No | No |
| Condom Compatibility | Natural Rubber Latex and Polyisoprene Condoms | Natural Rubber Latex and Polyisoprene Condoms |
| Shelf Life | 2 years | 12 months |
| Physical Characteristics Tested (appearance, color, odor) | Yes | Yes |
| pH Tested | Yes | Yes |
| Osmolality Tested | Yes | Yes |
| Biocompatibility Tested | Yes | Yes |
| Microbiology Tested (absence of pathogenic organisms, TAMC, and TYMC) | Yes | Yes |
| Antimicrobial Effectiveness Tested | Yes | Yes |

The subject device and predicate device have the same intended use (i.e., provides lubrication during intimate sexual activity). The subject device and predicate device have different technological characteristics including formulation and shelf life. These differences do not raise different questions of safety and effectiveness.

**VII) Summary of Performance Testing**

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility

Biocompatibility studies were performed in accordance with the *2023 FDA guidance document "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process"*, as follows*:*

- Cytotoxicity per ISO 10993-5:2009
- Sensitization per ISO 10993-10:2021
- Vaginal Irritation per ISO 10993-23:2021
- Acute Systemic Toxicity per ISO 10993-11:2017

The results of testing demonstrated the subject device is non-cytotoxic, non-sensitizing, non-irritating and is not acutely systemically toxic.

Condom Compatibility

Condom compatibility testing was performed per ASTM D7661-18 "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms". The results demonstrated that the LubriZenzs is compatible with natural rubber latex condoms and synthetic polyisoprene condoms and not compatible with polyurethane condoms.

Shelf-Life Testing

The results of real-time stability testing demonstrated that LubriZenzs is shown to have a 2 year shelf-life and met the device specifications as listed in Table 1 of this 510(k) Summary.

**VIII) Conclusion**

The results of the performance testing described above demonstrate that LubriZenzs is as safe and effective as the predicate device and support a determination of substantial equivalence.