July 14, 2026

Luwi, LLC
% Tyler Ting
Regulatory Director
Rook Quality Systems
1155 Mount Vernon Highway, Suite 800
Atlanta, Georgia 30338

Re: K253662
Trade/Device Name: Lixi (lxosfm1)
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: MSC
Dated: November 20, 2025
Received: November 20, 2025

Dear Tyler Ting:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

Reginald K. Avery -S

for
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253662

Device Name
Lixi (lxosfm1)

Indications for Use *(Describe)*
LIXI (lxosfm1) are used as a barrier when engaging in oral/vaginal and oral/anal sex to help reduce the transmission of bodily fluids, harmful pathogens, and sexually transmitted infections.

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 – K253662
In accordance with 21 CFR 807.92 the following summary information is provided:

Date Prepared: July 10, 2026

I. Contact Details

Applicant Name:	LUWI, LLC
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Applicant Contact Email:	lisa@getluwi.com
Correspondent Name:	Mr. Tyler Ting, MS, RAC-Devices Regulatory Director Rook Quality Systems
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Correspondent Telephone:	+1 (970) 404-1555
Correspondent Email:	tyler.ting@rookqs.com

II. Device Trade Name

Device Trade Name:	LIXI (lxosfm1)
Common Name:	Oral Dam
Regulation Number:	21 CFR 884.5300
Regulation Name:	Condom
Regulatory Class:	II
Product Code:	MSC (Barrier, Std, Oral Sex)

III. Legally Marketed Predicate Devices

510(k)	Trade Name	Product Code
K212928	Lorals	MSC

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

IV. Device Description Summary

LIXI (lxosfm1) are wearable, single-use, polyurethane oral dams that are placed over the vagina and/or anus during oral sexual contact. LIXI (lxosfm1) are designed similar to underwear, with a region that covers the genital region and a waistband to keep the dam in place, all made from the same polyurethane material.

V. Indications for Use

LIXI (lxosfm1) are used as a barrier when engaging in oral/vaginal and oral/anal sex to help reduce the transmission of bodily fluids, harmful pathogens, and sexually transmitted infections.

VI. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below compares the intended use and technological characteristics of the subject and predicate device.

Comparison Elements	Subject Device: LIXI (lxosfm1)	Predicate Device: Lorals K212928
Product Code, **Device Risk Classification**	MSC (Barrier, Std, Oral Sex) II	MSC (Barrier, Std, Oral Sex) II
Regulation Number	21 CFR 884.5300	21 CFR 884.5300
Regulation Name	Condom	Condom
Indications for Use	LIXI (lxosfm1) are used as a barrier when engaging in oral/vaginal and oral/anal sex to help reduce the transmission of bodily fluids, harmful pathogens, and sexually transmitted infections.	Lorals are used as a barrier when engaging in oral/vaginal sex and oral/anal sex to help reduce the transmission of bodily fluids, harmful pathogens, and sexually transmitted infections.
Material	Polyurethane	Natural rubber latex
Location of Use	Anus, vagina, oral cavity (mouth)	Anus, vagina, oral cavity (mouth)
Lubricated	No	No
Color	Colorless	Black
Fragrance/Flavor	None	Vanilla
Design & Dimensions	The length from end-to-end of LIXI (lxosfm1) measures 857 mm from the end of one tie or “ribbon” to the other end,	Gusset width: 163mm, 188mm, 213mm Gusset height: 228 mm Thickness: 0.07mm

	including the center gusset of 155 mm. Thickness: 0.0575mm Gusset: 155 mm x 255 mm Ties or “ribbons” form an adjustable waistband: 374.65 mm x 25.4 mm.	Lorals Height: 264 mm Waistband Width: 343 mm Waistband Height: Bikini: 61 mm Shortie 162 mm
Sterility	Non-Sterile	Non-Sterile
Shelf-life	1 year	2 years
Biocompatibility Tested?	Yes	Yes

The indications for use of the subject and predicate device are identical, and both devices have the same intended use (i.e., to act as a barrier when engaging in oral/vaginal and oral/anal sex). The technological differences between the subject and predicate device are the material, dimensions, shelf life, flavor, and color. These differences do not raise different questions of safety and effectiveness and can be addressed through performance testing.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Performance testing was performed on the subject device per the FDA recognized standard ISO 29942:2011 Prophylactic dams –Requirements and test methods. The following testing was performed:

- Dimensional Testing
- Tensile Testing and Elongation at Break
- Tear Resistance and Tearing Force
- Freedom from Holes and Visual Defects
- Packaging Integrity Testing
- Viral Penetration Testing

The bench testing was completed as outlined in the standard to support the 1-year shelf life.

As required, biocompatibility of the device was assessed per the recommendations outlined in the 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." The following testing was performed:

- Cytotoxicity (ISO 10993-5:2009)
- Irritation Testing (ISO 10993-10:2010)
- Sensitization (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2017)

All testing was acceptable

Conclusion

The results of the performance testing described above demonstrate that the LIXI (lxosfm1)'s is as safe and effective as the predicate device and supports a determination of substantial equivalence.