April 22, 2022

Brazen Goods Inc. dba Lorals
% Erin Gontang
Regulatory Specialist
AcKnowledge Regulatory Strategies LLC
2251 San Diego Avenue, B-257
San Diego, CA 92110

Re: K212928
Trade/Device Name: Lorals
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: MSC,
Dated: March 21, 2022
Received: March 22, 2022

Dear Erin Gontang:

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,

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

510(k) Number *(if known)*
K212928

Device Name
Lorals

Indications for Use *(Describe)*
Lorals 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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

DATE PREPARED
April 21, 2022

MANUFACTURER AND 510(k) OWNER
Brazen Goods Inc.
106 1/2 Judge John Aiso St. #305, Los Angeles, CA 90012, USA
Telephone: +1 (323) 813-4220
Official Contact: Melanie Cristol, Founder & CEO

REPRESENTATIVE/CONSULTANT
Erin A. Gontang, Ph.D.
Allison C. Komiyama, Ph.D., RAC
RQM+ Corp.
Telephone: +1 (412) 816-8253
Email: egontang@rqmplus.com
akomiyama@rqmplus.com
Website: www.rqmplus.com

DEVICE INFORMATION

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

PREDICATE DEVICE IDENTIFICATION
Lorals are substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K091769	Trust Dam/Line One Laboratories, Inc.	✓

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

DEVICE DESCRIPTION
Lorals are wearable, single-use, natural rubber latex oral dams that are placed over the vagina and/or anus during oral sexual contact. Lorals 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 natural rubber latex. The dams are available in two designs, Shortie and Bikini, which provide the same coverage of the genital region, but have different waistband heights, based on user preference.

Each design is available in 3 different gusset sizes. The dams are scented with vanilla fragrance and are provided in black only.

INDICATIONS FOR USE

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.

COMPARISON OF INDICATIONS FOR USE AND TECHNOLOGICAL CHARACTERISTICS

The intended use of the subject device, Lorals, and the predicate device, Trust Dams (K091769), are the same. Both the subject device and the predicate device are used as a barrier when engaging in oral/vaginal sex and oral/anal sex. **Table 1** below compares the technological characteristics of the subject device and the predicate device.

Table 1 Comparison of Technological Characteristics of the Subject and Predicate Devices.

	Lorals (Subject Device)	**Trust Dam (Predicate Device)**
Device Name	Lorals	Trust Dams
Manufacturer	Brazen Goods Inc.	Line One Laboratories Inc
510(k) Number	K212928	K091769
Regulatory Class	II	II
Regulation Number	21 CFR 884.5300	21 CFR 884.5300
Product Code	MSC (Barrier, Std, Oral Sex)	MSC (Barrier, Std, Oral Sex)
Regulation Name	Condom	Condom
Indications for Use	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.	The Line One Trust Dam is used as a barrier when engaging in oral/vaginal sex and oral/anal sex to help reduce the transmission of bodily fluids, harmful germs, and sexually transmitted diseases.
Material	Natural rubber latex	Natural rubber latex
Location of Use	Anus, vagina, oral cavity (mouth)	Anus, vagina, oral cavity (mouth)
Lubricated	No	No
Color	Black	Yellow, Red, Green
Fragrance/Flavor	Vanilla	Banana, Strawberry, Mint
Design & Dimensions	Rectangular sheet with integrated waistband Gusset width: 163 mm,	Rectangular sheet Width: 154 mm

	188 mm, or 213 mm Gusset Height: 228 mm Thickness: 0.07 mm Lorals Height: 264 mm Waistband Width: 343 mm Waistband Height: Bikini: 61 mm Shortie: 162 mm	Height: 250 mm Thickness: 0.07 mm
Mechanical Properties	Tested in accordance with ISO 29942:2011, including the following tests: Tensile strength Elongation at break Tearing force Tear resistance Freedom from holes	Tested in accordance with ASTM D3492:2008
Sterility	Non-Sterile	Non-Sterile
Shelf-life	2 years	5 years
Biocompatibility Tested?	Yes	Yes

The intended use of Lorals is the same as the Trust Dam. Differences in technological characteristics include the dimensions, shape, packaging, color and flavor additives, and shelf life. However, these differences between the subject and predicate device, as described in **Table 1**, do not raise different questions of safety or effectiveness.

SUMMARY OF NON-CLINICAL TESTING

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

The bench testing was completed as outlined in the standard to support the 2-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 test results were acceptable.

CONCLUSION

The results from the non-clinical bench testing above demonstrate that Lorals dams are as safe and effective as the predicate device and support a determination of substantial equivalence.