March 28, 2022

Sanctuary Health Sdn. Bhd.
Sumethi Selavaraju
QAQC cum RA Deputy Manager
No. 16, Persiaran Perindustrian Kanthan 1,
Kawasan Perindustrian Kanthan
Chemor, Perak 31200
Malaysia

Re: K212037
Trade/Device Name: SancDam™ Latex Oral Dam
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: MSC
Dated: February 18, 2022
Received: February 24, 2022

Dear Sumethi Selavaraju:

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)*
K212037

Device Name
SancDam™ Latex Oral Dam

Indications for Use *(Describe)*
The SancDam™ Latex Oral Dam is 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.

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SancDam™ Oral Latex Dam – Traditional 510(k)

510(k) Summary

a. Submitter and Device Information

Category	Comments
Submitter	**Sanctuary Health Sdn. Bhd.** No. 16, Persiaran Perindustrian Kanthan 1, Kawasan Perindustrian Kanthan, 31200 Chemor, Perak Darul Ridzuan, Malaysia. Tel No: +605 - 201 2800 Fax No: +605 - 201 7800
Correspondent Contact Information	Sumethi Selvaraju, QAQC cum RA Deputy Manager Tel: +605-201 2800 ext. 204 E-mail: regulatory@sanctuaryhealth.com.my Add: No. 16, Persiaran Perindustrian Kanthan 1, Kawasan Perindustrian Kanthan, 31200 Chemor, Perak Darul Ridzuan, Malaysia.
Device Proprietary Name	SancDam™ Latex Oral Dam
Device Common Name	Latex Dam
Device Classification Number	21 CFR 884.5300
Device Classification Name	Condom
Device Class	II
Product Code	MSC (Barrier, Std, Oral Sex)

Predicate Device	
Predicate Device Manufacturer	Line One Laboratories, Inc.
Predicate Device Common Name	Latex Dam
Predicate Device Proprietary Name	Line One Trust Dam
Predicate Device Premarket Notification #	K091769
Predicate Device Classification	21 CFR 884.5300 - Condom
Predicate Device Class	II
Predicate Device Product Code	MSC (Barrier, Std, Oral Sex)
Design-related recall	The predicate device has not been subject to a design-related recall.

b. Date Summary Prepared

March 24, 2022

c. Description of Device

The SancDam™ Latex Oral Dam are rectangular shaped, non-porous, intact polymer films made of natural rubber latex that are placed over the vagina or anus during oral sexual contact. The dam is used as a physical barrier to cover the external female genitalia or the anal area.

The SancDam™ has a smooth surface on both sides. The size of the SancDam™ is 155 mm (± 5 mm) by 254 mm (± 5 mm) by 0.07 mm (± 0.02 mm).

The SancDam™ available in 4 different flavors and colors versions as listed below:

Color	Flavor
Pink	Strawberry
Green	Mint
Yellow	Vanilla
Purple	Grape

d. Indications for Use

The SancDam™ Latex Oral Dam is 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.

e. Comparison of Indications for Use and Technological Characteristics with the Predicate Device

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

	SancDam™ Latex Oral Dam (Subject Device)	**Line One Trust Dam (Predicate Device)**
Device Name	SancDam Latex Oral Dam	Trust Dams
Manufacturer	Sanctuary Health Sdn. Bhd.	Line One Laboratories, Inc.
510(k)	K212037	K091769
Regulatory Class	II	II
Regulation number	21 CFR 884.5300	21 CFR 884.5300
Product Code	MSC	MSC

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SancDam™ Oral Latex Dam – Traditional 510(k)

Classification Name	Barrier, Std, Oral Sex	Barrier, Std, Oral Sex
Indications for Use	The SancDam™ Latex Oral Dam is 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.	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.
Design & dimensional aspects	Thin, rectangular sheet with smooth surface both sides 155 mm x 254 mm, Thickness 0.07 mm	Thin, rectangular sheet with smooth surface both sides 154 mm x 250 mm, Thickness 0.07 mm
Material	Natural rubber latex	Natural rubber latex
Lubricated	No	No
Color	Yellow, Pink, Purple, Green	Yellow, Red, Green
Fragrance/Flavor	Vanilla, Strawberry, Grape, Mint	Banana, Strawberry, Mint
Mechanical Properties	Tested in accordance with ISO 29942:2011, including the following tests: • Tensile strength • Elongation at break • Tearing force • Freedom from holes • Tear resistance	Tested in accordance with ASTM D3492:2008
Sterile	No	No
Body Location Target Area	Anal, vaginal, oral cavity (mouth)	Anal, vaginal, oral cavity (mouth)
Single Use	Yes	Yes
Shelf-life	2 years	5 years
Biocompatibility Tested?	Yes	Yes

The intended use of the subject device, SancDam™ Latex Oral Dam, and the legally marketed predicate devices, Line One Trust Dam (K091769), are the same. Both the subject device and the predicate device 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. The differences between the subject and predicate device include the

colors, flavors, and shelf life. However, these differences in technological characteristics do not raise different questions of safety or effectiveness.

f. Nonclinical Testing

The following non-clinical testing was completed on the SancDam™ Latex Oral Dam:

- Per ISO 29942:2011 *Prophylactic dams -- Requirements and test methods*
  - 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 on aged and unaged samples to support the 2-year shelf life.

- Per the 2020 FDA guidance *Use of International Standard ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"*:
  - 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.

g. Conclusion

The results from the non-clinical bench testing above demonstrate that the SancDam™ Latex Oral Dam are as safe and effective as the predicate device and support a determination of substantial equivalence.