August 5, 2021

Pamco Distributing, Inc.
% Catriona Boyd
Senior Medical Device Consultant
Ironstone Product Development
250 Carlaw Avenue, Suite 108
Toronto, Ontario M4M 3L1
Canada

Re: K203727
Trade/Device Name: Harmony® Latex Dams, Harmony® Polyisoprene Dams
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: MSC
Dated: July 2, 2021
Received: July 6, 2021

Dear Catriona Boyd:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203727

Device Name
Harmony® Latex Dams
Harmony® Polyisoprene Dams

Indications for Use *(Describe)*
The Harmony® Latex & the Harmony® Polyisoprene Dams 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.

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510(k) SUMMARY

Harmony® Latex and Harmony® Polyisoprene Dams

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Pamco Distributing Inc.
231 Arnold Street
Kitchener, ON, Canada
N2H 6E8
Phone: +1-519-648-2200
Contact Person: Annette Maclean

Date Prepared: August 3, 2021

Name of Device

Harmony® Latex Dams
Harmony® Polyisoprene Dams

Device Classification and Product Code

Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: Class II
Product Code: MSC (Barrier, Std, Oral Sex)

Predicate Device

Trust Dam (K091769)

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

Indications for Use

The Harmony® Latex & the Harmony® Polyisoprene Dams 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.

Device Description

The Harmony® Latex and Harmony® Polyisoprene Dams are rectangular shaped non-porous, intact polymer film that are placed over the vagina or anus during oral sexual contact. The dam provides coverage to the external female genitalia or to the anal area and acts as a physical barrier to infectious agents responsible for the transmission of sexually transmitted infections (STIs). Both Harmony® Latex and Harmony® Polyisoprene Dams are 152.4 mm (6") x 254 mm (10") and 0.12 mm thick. The Harmony® Latex Dam contains natural polyisoprene rubber and the Harmony® Polyisoprene Dam contains synthetic polyisoprene rubber. The dams are slightly scented with vanilla fragrance and are provided in natural color.

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

The intended use of the subject devices, Harmony® Latex & the Harmony® Polyisoprene Dams, and the predicate device, Trust Dams (K091769), are the same. Both the subject devices 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. **Table 1** below compares the technological characteristics of the subject devices and the predicate device.

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

	Harmony® Dams (Subject Devices)	**Trust Dam (Predicate Device)**
Device Name	Harmony® Latex Dams Harmony® Polyisoprene Dams	Trust Dams
Manufacturer	Pamco Distributing Inc.	Line One Laboratories Inc
510(k) Number	K203727	K091769
Regulatory Class	II	II
Regulation Number	21 CFR 884.5300	21 CFR 884.5300
Product Code	MSC	MSC
Classification Name	Barrier, Std, Oral Sex	Barrier, Std, Oral Sex
Intended Use	The Harmony® Latex & the Harmony® Polyisoprene Dams 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 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.
Nominal Dimensions	152.4 mm X 254 mm, Thickness- 0.12 mm	154 mm X 250 mm, Thickness- 0.07 mm
Material	*Harmony® Latex Dams:* Natural rubber latex *Harmony® Polyisoprene Dams:* Synthetic polyisoprene	Natural rubber latex
Lubricated	No	No
Color	Natural Color / No Dye Added	Yellow, Red, Green
Fragrance/Flavour	Vanilla	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
Sterility	Non-sterile	Non-sterile
Shelf-life	3 years	5 years
Biocompatibility Tested?	Yes	Yes

The intended use of the Harmony® Latex & the Harmony® Polyisoprene Dams is the same as the Trust Dam. The differences between the subject and predicate device include the materials (polyisoprene), colors, flavors, and shelf life. However, these differences in technological characteristics do not raise different questions of safety or effectiveness.

Summary Discussion of Non-Clinical Data

The following non-clinical testing was completed on the Harmony® Latex and Harmony® Polyisoprene Dams:

- 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
- Viral Barrier Properties
- Packaging Integrity Testing
- 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.

Conclusions

The results from the non-clinical bench testing above demonstrate that the Harmony® Latex Dams and Harmony® Polyisoprene Dams are as safe and effective as the predicate device and support a determination of substantial equivalence.