February 17, 2022

Titan Condoms LLC
℅ George Hattub
Senior Project Manager
Medicsense USA
291 Hillside Avenue
Somerset, MA 02726

Re: K210208
Trade/Device Name: Titan Condoms
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: January 17, 2022
Received: January 20, 2022

Dear George Hattub:

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
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210208

Device Name
Titan Condoms

Indications for Use *(Describe)*

The Titan Condoms are indicated for use for contraceptive and prophylactic purposes (to help prevent pregnancy and the transmission of 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 – K210208

Submitter Address:	Titan Condoms LLC 1950 Elkhorn Ct. Apt. 210 San Mateo, CA 94403
Submitter Contact Person:	Mr. Neville Muringayi, CEO neviilemuringayi@gmail.com (951) 746-6130
Date Prepared:	February 16, 2022
Device Name:	Titan Condoms
Common name:	Male Natural Rubber Latex Condom
Regulation Name:	Condom
Regulation Number:	21 CFR 884.5300
Product Code:	HIS (Condom)
Regulatory Class:	II
Predicate Device:	K122219 – TheyFit Male Condom The predicate device has not been subject to a design-related recall.
Device Description:	Titan Condoms are made of a natural latex sheath which completely covers the penis with a closely fitted membrane. The condom is shaped with a reservoir end and a cylinder shape. Titan condoms are available in a range of sizes, with different length and width combinations. Surface textures include smooth, dotted, and ribbed. Titan Condoms are provided pre-lubricated with a silicone-based lubricant. **Table 1** provides the dimensions and features of each condom variant.

Table 1. Features for each condom variant

Corresponding Condom Size (mm)	Condom Thickness (mm)	Lubricant	Reservoir Tip	Texture Features
180 x 49	0.05 – 0.07	Silicone-Based	Yes	N/A
180 x 52	0.05 – 0.07	Silicone-Based	Yes	Dotted
180 x 52	0.05 – 0.07	Silicone-Based	Yes	Ribbed
185 x 53	0.05 – 0.07	Silicone-Based	Yes	N/A
180 x 53	0.05 – 0.06	Silicone-Based	Yes	N/A
180 x 53	0.08	Silicone-Based	Yes	N/A
185 x 57	0.05 – 0.07	Silicone-Based	Yes	N/A
193 x 60	0.05 – 0.07	Silicone-Based	Yes	N/A
223 x 64	0.05 – 0.07	Silicone-Based	Yes	N/A
223 x 69	0.05 – 0.07	Silicone-Based	Yes	N/A

Indications for Use: The Titan Condoms are indicated for use for contraceptive and prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections).

Comparison of Intended Use and Technological Characteristics: A comparison of the intended use and technological features of the subject and predicate devices are described in Table 2 below:

Table 2. Comparison of technological characteristics

	Subject Device Titan Condoms K210208	**Predicate Device TheyFit Male Condoms K122219**	**Comparison**
Product Code	HIS	HIS	Same
Indications for Use	The Titan Condoms are indicated for use for contraceptive and prophylactic purposes (to help prevent pregnancy the transmission of sexually transmitted infections.	The TheyFit Male Condom is used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections)	The indications for use and intended use of the subject and predicate devices are the same.
Condom Material	Natural Rubber Latex	Natural Rubber Latex	Same
Design	Varied sizes with different length, width, and thickness combinations. Cylindrical with reservoir end Smooth, dotted, and ribbed surface textures.	Varied sizes with different length/width combinations. Cylindrical with reservoir end Surface texture information not known as not stated in the predicate 510(k) Summary.	**Different:** The subject and predicate devices are both provided in different length and width configurations. Versions of the subject device are also provided with varying thickness and surface texture. These differences do not raise different questions of S&E.
Fitting Kit to Determine Correct Size	Yes	Yes	Same
Maximum Length	180 - 223 mm	163 - 208 mm	**Different:** The subject and predicate devices have different maximum lengths. The subject devices are within the range of maximum lengths of the predicate with the exception of subject device versions with maximum lengths of 223 mm. This difference in

			maximum length does not raise different questions of safety and effectiveness (S&E).
Maximum Width	49 - 69 mm	49 - 64 mm	**Different:** The subject and predicate devices have different maximum widths. The subject device includes one version with a maximum width of 69 mm. This difference in maximum width does not raise different questions of safety and effectiveness (S&E).
Lubricant	Silicone based	Silicone based	Same
Color Additives	none	none	Same
Flavor Additives	none	none	Same
Single Use Device	Yes	Yes	Same
Shelf Life	5 years	5 years	Same

As shown in the table above, the subject and predicate devices have the same indications for use and intended use. The technological characteristics of the subject and predicate device are different as the subject devices have a larger maximum length and width than the predicate devices, and versions with varying thickness. In addition, versions of the subject device include ribbed or dotted textures that may differ from the predicate device. These differences in technological characteristics do not raise different questions of safety and effectiveness.

Summary of Clinical Testing:

A prospective clinical study was conducted to evaluate the slippage and breakage rate of the 64 mm and 69 mm condoms. The clinical study was based on ISO 29943-1:2017 Condoms - Guidance on Clinical Studies-Part 1: Male Condoms.

Eligible participants used the Titan Size Guide to determine their penis girth measurements, which was used to determine if they would test the 64 mm or 69 mm condom. Each couple was to use three condoms within two consecutive weeks. Each couple completed an online individual condom use case report form. Clinical endpoints were clinical condom slippage and breakage during use, participant's satisfaction, and genitourinary adverse events. The pre-specified endpoint was a total clinical failure rate <5%.

The baseline demographic information for participants in this study are shown in **Table 3.**

Table 3. Trial participant baseline demographics

Parameter	Percentage of Participants
Age	
18 to 24	5%
25 to 29	23%
30 to 34	19%
35 to 39	33%
40 to 45	20%
Ethnicity	
White/Caucasian	48%
African/American	22%
Hispanic/Latino	20%
Asian or Pacific Islander	5%
More than one	5%

Study results showed a clinical failure rate for the condom with a width of 64 mm of 0%. The condom with a width of 69 mm had a clinical failure rate of 3.1%. Therefore, Titan Condoms met the pre-defined total clinical failure endpoint of <5%.

Summary of Non-Clinical Performance Testing

The following studies have been performed to support substantial equivalence to the predicate device:

Biocompatibility

Biocompatibility testing was performed in accordance with the 2020 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." Testing included the following assessments:

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

The results of this testing demonstrated that the subject devices are biocompatible.

Physical Testing

All Titan Condom versions were tested and met all the requirements of ISO 4074:2015 - *Natural rubber latex male condoms – Requirements and test methods.*

Shelf-Life

Titian Condoms have a five-year shelf life based on the results of real-time and accelerated stability evaluations conducted as required in 21 CFR 801.435. All samples met predefined acceptance criteria.

Conclusion: The results of the performance testing described above demonstrate that the Titan Condoms are as safe and effective as the predicate device and supports a determination of substantial equivalence.