

**DE NOVO CLASSIFICATION REQUEST FOR
ONE MALE CONDOM**

REGULATORY INFORMATION

FDA identifies this generic type of device as:

External condom for anal intercourse or vaginal intercourse. An external condom for anal intercourse or vaginal intercourse is a barrier device which covers the penis and is used to prevent the transmission of sexually transmitted infections (when used for anal intercourse or vaginal intercourse) and for contraception (when used for vaginal intercourse). This classification does not include condoms intended for vaginal intercourse only.

NEW REGULATION NUMBER: 21 CFR 884.5305

CLASSIFICATION: Class II

PRODUCT CODE: QRZ

BACKGROUND

DEVICE NAME: ONE Male Condom

SUBMISSION NUMBER: DEN210034

DATE DE NOVO RECEIVED: August 26, 2021

SPONSOR INFORMATION:

Global Protection Corp.
12 Channel Street
Boston, MA 02210

INDICATIONS FOR USE

The ONE Male Condom is indicated as follows:

The ONE Male Condom is used for contraception to help reduce the risk of pregnancy during vaginal intercourse and for prophylactic purposes to help reduce the transmission of sexually transmitted infections (STIs) during vaginal or anal intercourse. The ONE Male Condom should be used with a condom compatible lubricant when used for anal intercourse.

LIMITATIONS

Warnings

- The condom cannot be used multiple times and is limited to one sex act. One sex act refers to one instance of vaginal intercourse or anal intercourse.
- Make sure there is adequate lubrication. An adequate amount of condom compatible lubricant should be used during anal intercourse to help reduce the risk of condom failure.

Precautions

- This product contains natural rubber latex which may cause allergic reactions.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS AND PRECAUTIONS.

DEVICE DESCRIPTION

The ONE Male Condom is a natural rubber latex sheath that completely covers the penis. The condom is straight walled with a reservoir tip and is silicone lubricated.

Figure 1 is an image of the basic schematic of the condom.

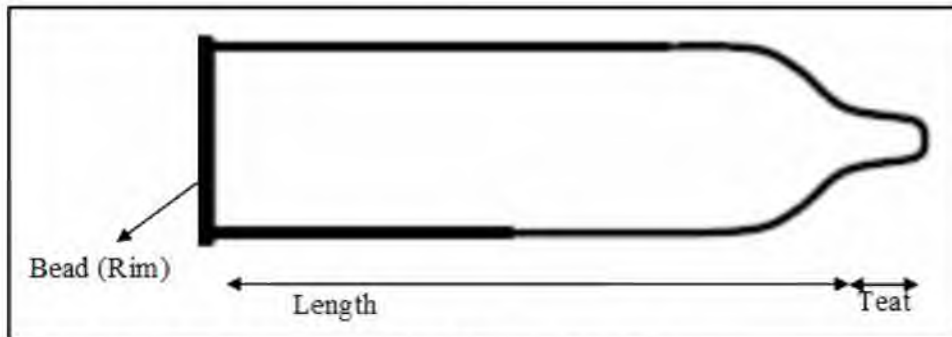


Figure 1: Schematic image of the ONE Male Condom

The ONE Male Condom is available in 56 sizes and consists of three different condom types, standard, thin, and fitted. It is identical in size, material composition and manufacturing to condoms cleared in K081886, K122219, K141059, and K150072.

Table 1 provides a list of all sizes available for the One Male Condom and their associated nominal length, width, and thickness.

Model number	Nominal length	Nominal width	Nominal thickness	Condom type
O77	165mm	49mm	0.074mm	Fitted
O88	165mm	51mm	0.074mm	Fitted
O99	165mm	53mm	0.074mm	Fitted
O11	165mm	55mm	0.074mm	Fitted
O17	165mm	57mm	0.074mm	Fitted

Model number	Nominal length	Nominal width	Nominal thickness	Condom type
O21	165mm	60mm	0.074mm	Fitted
O22	165mm	64mm	0.074mm	Fitted
N88	180mm	51mm	0.074mm	Fitted
N99	180mm	53mm	0.074mm	Fitted
N11	180mm	55mm	0.074mm	Fitted
N17	180mm	57mm	0.074mm	Fitted
N21	180mm	60mm	0.074mm	Fitted
N22	180mm	64mm	0.074mm	Fitted
D11	195mm	55mm	0.074mm	Fitted
D17	195mm	57mm	0.074mm	Fitted
D21	195mm	60mm	0.074mm	Fitted
D22	195mm	64mm	0.074mm	Fitted
Z11	210mm	55mm	0.074mm	Fitted
Z17	210mm	57mm	0.074mm	Fitted
Z21	210mm	60mm	0.074mm	Fitted
Z22	210mm	64mm	0.074mm	Fitted
E55	123mm	45mm	0.074mm	Fitted
E66	123mm	47mm	0.074mm	Fitted
E77	123mm	49mm	0.074mm	Fitted
E88	123mm	51mm	0.074mm	Fitted
E99	123mm	53mm	0.074mm	Fitted
E11	123mm	55mm	0.074mm	Fitted
E17	123mm	57mm	0.074mm	Fitted
E21	123mm	60mm	0.074mm	Fitted
B55	133mm	45mm	0.074mm	Fitted
B66	133mm	47mm	0.074mm	Fitted
B77	133mm	49mm	0.074mm	Fitted
B88	133mm	51mm	0.074mm	Fitted
B99	133mm	53mm	0.074mm	Fitted
B11	133mm	55mm	0.074mm	Fitted
B17	133mm	57mm	0.074mm	Fitted
B21	133mm	60mm	0.074mm	Fitted
B22	133mm	64mm	0.074mm	Fitted
S55	143mm	45mm	0.074mm	Fitted
S66	143mm	47mm	0.074mm	Fitted
S77	143mm	49mm	0.074mm	Fitted
S88	143mm	51mm	0.074mm	Fitted
S99	143mm	53mm	0.074mm	Fitted
S11	143mm	55mm	0.074mm	Fitted
S21	143mm	60mm	0.074mm	Fitted
S22	143mm	64mm	0.074mm	Fitted
M66	153mm	47mm	0.074mm	Fitted
M77	153mm	49mm	0.074mm	Fitted

Model number	Nominal length	Nominal width	Nominal thickness	Condom type
M88	153mm	51mm	0.074mm	Fitted
M99	153mm	53mm	0.074mm	Fitted
M11	153mm	55mm	0.074mm	Fitted
M17	153mm	57mm	0.074mm	Fitted
M21	153mm	60mm	0.074mm	Fitted
M22	153mm	64mm	0.074mm	Fitted
P53S UT	180mm	53mm	0.058mm	Thin
P53S	185mm	53mm	0.074mm	Standard

Table 1: ONE Male Condom sizes and dimensions

For the fitted condom type, to determine the appropriate condom size, a fitting tool (**Figure 2**) is available online. Prior to purchasing the fitted condom, the user measures the length of their erect penis and then its width. Each length and width have an associated letter and number, which translates to a model number corresponding to a size in **Table 1**. **Figure 2** is an image of the fitting kit.

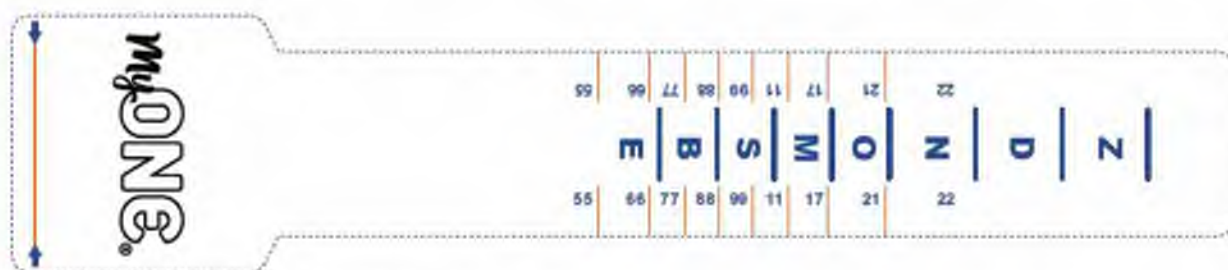


Figure 2: ONE Male Condom fitting tool

To mitigate the risk of condom failure, the ONE Male Condom should be used with a condom-compatible lubricant during anal intercourse.

The ONE Male Condom conforms to ISO 4074-15, *Natural rubber latex male condoms – Requirements and test methods* and ASTM D3492-16, *Standard Specification for Rubber Contraceptives (Male Condoms)*.

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

The ONE Male Condom is categorized as a surface device that contacts both the skin and mucosal membrane for a limited (<24 hour) contact duration with the potential for repeat exposure. The ONE Male Condom is identical in material composition and manufacturing to condoms cleared in K081886, K122219, K141059, and K150072. Therefore, biocompatibility testing completed on the cleared condoms was leveraged to support the biocompatibility of the ONE Male Condom.

The following biocompatibility endpoints were assessed:

Endpoint	Test Method
Cytotoxicity	MEM Elution Test ISO 10993-5:2009
Sensitization	Guinea Pig Maximization ISO 10993-10:2010
Irritation	Vaginal Irritation Test ISO 10993-10:2010
Acute Systemic Toxicity	ISO 10993-11:2006 Note: FDA currently recognizes the 2017 version of this standard. The sponsor provided a comparison between the 2006 and 2017 version of the standard and justified that the differences should not affect interpretation of the test data.

The results demonstrate that the ONE Male Condom is biocompatible.

SHELF-LIFE/STERILITY

The ONE Male Condom is a non-sterile, single-use device.

The shelf-life for the ONE Male Condom has been established at five years based on two accelerated aging studies, as described in K081886, K122219, K141059, and K150072. One accelerated aging study was conducted for 7 days at 70°C, and the second accelerated aging study was conducted for 90 days at 50°C.

To support the five year shelf-life, the sponsor conducted dimensional analysis, airburst testing, freedom from holes, visible defects, and package integrity testing per ISO 4074-15 and ASTM D3492-16 on samples of each condom size. Following exposure to the accelerated aging conditions, the ONE Male Condom met the acceptance criteria outlined in ISO 4074-15 and ASTM D3492-16 for each test as described in the Performance Testing – Bench section below. The results demonstrate that the ONE Male Condom has acceptable package integrity and functional performance over the duration of its five year shelf life.

While the ONE Male Condom is not subject to 21 CFR 801.435, User labeling for latex condoms, the shelf-life testing completed is consistent with the testing outlined that regulation.

PERFORMANCE TESTING - BENCH

The ONE Male Condom is identical in technological specifications to the condoms cleared in K081886, K122219, K141059, and K150072. Therefore, bench performance testing completed on the cleared condoms were leveraged to support the ONE Male Condom.

The prior bench testing conducted included dimensional analysis (nominal width, length, and thickness), water leak testing, airburst testing (pressure and volume) and testing to demonstrate freedom from holes. Performance testing was conducted on three lots of each proposed size of

the ONE Male Condom. The sponsor evaluated 125 samples of each proposed size. Consistent with ISO 4074-15 and ASTM D3492-16, the acceptance criterion for airburst pressure was a minimum of 1 kPa, and the acceptance criteria for airburst volume ranged from 11-22 dm³ based on condom size. The acceptance criteria for the remaining tests are consistent with ISO 4074-15 and ASTM D3492-16 and are established based on an acceptance quality limit (AQL) consistent with lot size. The results of testing demonstrated that the ONE Male Condom met all specifications.

Airburst properties are the key mechanical performance specifications for natural rubber latex condoms, and the airburst specifications identified in the ISO 4074-15 and ASTM D3492-16 standard were originally established to support adequate mechanical performance during vaginal intercourse. The airburst specifications in ISO 4074-15 and ASTM D3492-16 were set such that condoms need to meet a significantly higher mechanical performance threshold than necessary to ensure mechanical safety during vaginal intercourse. Based on the comparable rates of clinical breakage and slippage for anal intercourse compared to vaginal intercourse observed in the pivotal clinical study below, the ISO 4074-15 and ASTM D3492 airburst specifications are sufficient to support mechanical performance of the ONE Male Condom during anal intercourse.

The results of testing demonstrate that One Male Condom performs has adequate mechanical performance under anticipated conditions of use.

Future devices that fall within 21 CFR 884.5305 may have a different design, material, size, etc. compared to the ONE Male Condom. Additional performance testing may be needed for those future devices to demonstrate substantial equivalence (e.g., viral penetration testing for synthetic condoms to demonstrate the device is an effective barrier to sexually transmitted infections).

SUMMARY OF CLINICAL INFORMATION

To support the safety and effectiveness of the ONE Male Condom for anal or vaginal intercourse, the sponsor conducted a clinical study to assess condom failures during anal intercourse among MSM (men who have sex with men) and during vaginal intercourse among MSW (men who have sex with women). The clinical study results were published in 2019 in the E Clinical Medicine Journal in a publication titled, “Levels of clinical condom failure for anal sex: A randomized cross-over trial.” The study design is consistent with ISO 29943-1:2017 *Condoms — Guidance on clinical studies — Part 1: Male Condoms, clinical function studies based on self-reports*.

The study was conducted in Atlanta, Georgia at two sites of the Rollins School of Public Health at Emory University.

Study participants received the three types of the ONE Male Condom: standard condoms, thin condoms, and the fitted condoms (n=5 of each type of condom, n=15 total). All condoms were manufactured from natural rubber latex and had 510(k) clearance. The three types of condoms evaluated were as follows:

- Standard condoms that were 185 ±10 mm length, 53 ±2 mm width, and 70 ±10 µm thick

- Thin condoms that were of identical width and length to the standard condoms, but 50 ± 5 μm thick
- Fitted condoms (54 available sizes; participants determined size based on fitting tool)

Study participants were trained on the correct use of condoms. Both the study participants and the study investigators were blinded on condom assignment.

Packets of 10 ml water-based, condom-compatible lubricant were distributed with the condoms. Study participants were instructed to only use study lubricant when using condoms. Based on guidance from the World Health Organization, all MSM study participants were instructed to use the study lubricant for all anal sex acts and MSW were instructed to use the study lubricant for vaginal sex acts as needed or desired.

Study participants were randomized to 1 of 6 orders of condom types to be used sequentially. Each participant was given five of each type of study condom (standard, thin, fitted) and had 2 weeks to use all five condoms of one condom type.

If all five condoms in a set were used by the end of the 2-week period, participants were crossed over to the next condom type. If not, participants were given an additional 2-week period to use the remaining condoms of that type. Therefore, participants were enrolled for a minimum of 6 weeks and a maximum of 12 weeks.

Study participants completed a self-administered electronic survey to collect baseline and demographic information. Study participants were trained on use of an electronic daily coital diary used to track sexual activity between visits. The biweekly study visits collected information on the previous set of condoms used, adverse events (AEs), and prepared the participants for the next set of study condoms to be used.

Inclusion & Exclusion Criteria:

Inclusion criteria:

1. Age 18-54
2. Lives in or near Atlanta metropolitan statistical area
3. Plans to be in Atlanta for the majority of the 12 weeks of enrollment
4. Able to independently complete survey instruments in English
5. Male sex at birth
6. Currently identifies as male
7. (a) For MSM, self-report to have only had sex with men in the past four weeks
(b) For MSW, self-report to have only had sex with women in the past four weeks
8. Self-report no transgender sex partners in the past four weeks
9. (a) For MSM, self-report at least one anal sex act in the past four weeks
(b) For MSW, self-report at least one vaginal sex act in the past four weeks
10. (a) For MSM, self-report intends to have sex only with men in the next 12 weeks
(b) For MSW, self-report intends to have sex only with women in the next 12 weeks
11. For MSM, self-reports an insertive role in the past four weeks or willing to be the insertive partner when using study condoms for anal sex

12. Willing and able to have sex using a latex condom provided by study
13. For MSW, report that current partner is not currently pregnant
14. For MSW, report that current partner does not desire to become pregnant currently or in the next 12 weeks
15. Consistently able to maintain an erection while using condoms
16. Not allergic to latex
17. Current partner(s) not allergic to latex
18. No genital piercings
19. (a) For MSW, female current partner(s) does (do) not have vaginal piercings
(b) For MSM, male current partner(s) does (do) not have anal piercings
20. Current partner(s) not known to be HIV-positive
21. Self-report absence of sexually transmitted infections, including HIV
22. Willing to provide at least two means of contact
23. Willing to only use lubricant provided by study
24. Not allergic to water-based lubricant
25. Current partner(s) not allergic to water-based lubricant
26. Negative HIV rapid test result or confirmed negative HIV test at baseline
27. Willing to use a fitting tool to determine penile dimensions and report results to study staff.

Exclusion criteria:

1. <18 years of age or >54 years of age
2. Does not live in or near Atlanta metropolitan statistical area
3. Does not plan to be in Atlanta for the majority of the 12 weeks of enrollment
4. Unable to independently complete survey instruments in English
5. Not male sex at birth
6. Does not currently identify as male
7. Self-report to have had sex with both men and women in the past four weeks
8. Self-report transgender sex partners in the past four weeks
9. Self-report no anal (MSM) or vaginal (MSW) sex act in the past four weeks
10. Self-report intends to have sex with both men and women in the next 12 weeks
11. Never the insertive partner for anal sex or not willing to be the insertive partner when using study condoms for anal sex
12. Not willing or unable to have sex using a latex condom provided by study
13. Plans to not have sex in the next four weeks
14. For MSW, report that current partner is currently pregnant
15. For MSW, report that current partner desires to become pregnant currently or in the next 12 weeks
16. Unable to consistently maintain an erection while using condoms
17. Allergic to latex
18. Current partner(s) allergic to latex
19. Genital piercings
20. For MSW, female current partner(s) has (have) vaginal piercings
21. For MSM, male current partner(s) has (have) anal piercings
22. Current partner(s) known to be HIV-positive
23. Self-report presence of sexually transmitted infections, including HIV

24. Confirmed HIV positive at baseline
25. Not willing to provide at least two means of contact
26. Not willing to only use lubricant provided by study
27. Allergic to water-based lubricant
28. Current partner(s) allergic to water-based lubricant
29. Not willing to use a fitting tool to determine penile dimensions.

Study Endpoints:

The primary endpoint for the study was total clinical failure as assessed through an electronic daily coital diary. The total condom failure rate was defined as the number of slippage, breakage, or both slippage and breakage events that occurred over the total number of sex acts performed. The primary endpoint was reported separately for the MSM and the MSW study arms. In addition to total clinical failure, the slippage, breakage, and total clinical failure rates were reported for each condom type (standard, thin, and fitted) within the MSM and MSW arms.

The study did not include any pre-specified statistical hypotheses. Descriptive statistics were reported for all endpoints. The sponsor used logistical mixed effects models to account for the crossover study design.

Analysis Populations:

An intention-to-treat (ITT) analysis was utilized for the primary endpoint and included any anal sex acts among MSM and any vaginal sex acts among MSW in which a study condom was used.

A per-protocol analysis was also conducted that used the above criteria but excluded sex acts for which lubricant was used incorrectly, including 1) lubricant inside of the condom, 2) use of condom incompatible lubricant, or 3) not using any lubricant (for the MSM arm only).

Study Results:

Participant Disposition

The study enrolled 252 MSM and 252 MSW. Participants reported a total of 4,884 anal or vaginal sex acts using the condoms provided in the study.

A total of 13,524 individuals were assessed for eligibility through field-based screening. Of the 2,819 initially eligible individuals, 1,037 (36.8%) completed a phone screen to determine eligibility. Of the 1,037 individuals who completed a phone screen, 681 were eligible for the study, and 542 attended a baseline visit. Of the 542 who attended the baseline visit, 504 were enrolled in the trial and received a randomized crossover order (252 MSM arm and 252 MSW arm). Among all enrolled participants in each arm, 200 MSM (79.4%) and 209 MSW (82.9%) were retained until the end of the study.

Of the total enrolled per arm, 43 MSM (17.1%) and 35 MSW (13.9%) were study stopped, and 9 MSM (3.6%) and 8 MSW (3.2%) were lost to follow-up. Among MSM, the most common reasons for study stopping were voluntary withdrawal (n = 27), new HIV positive partner, STI

symptoms or recent diagnosis, and moving out of the study area. Among MSW, the most common reasons for study stopping were voluntary withdrawal and moving out of the study area.

Figure 3 summarizes the participant disposition throughout the study.

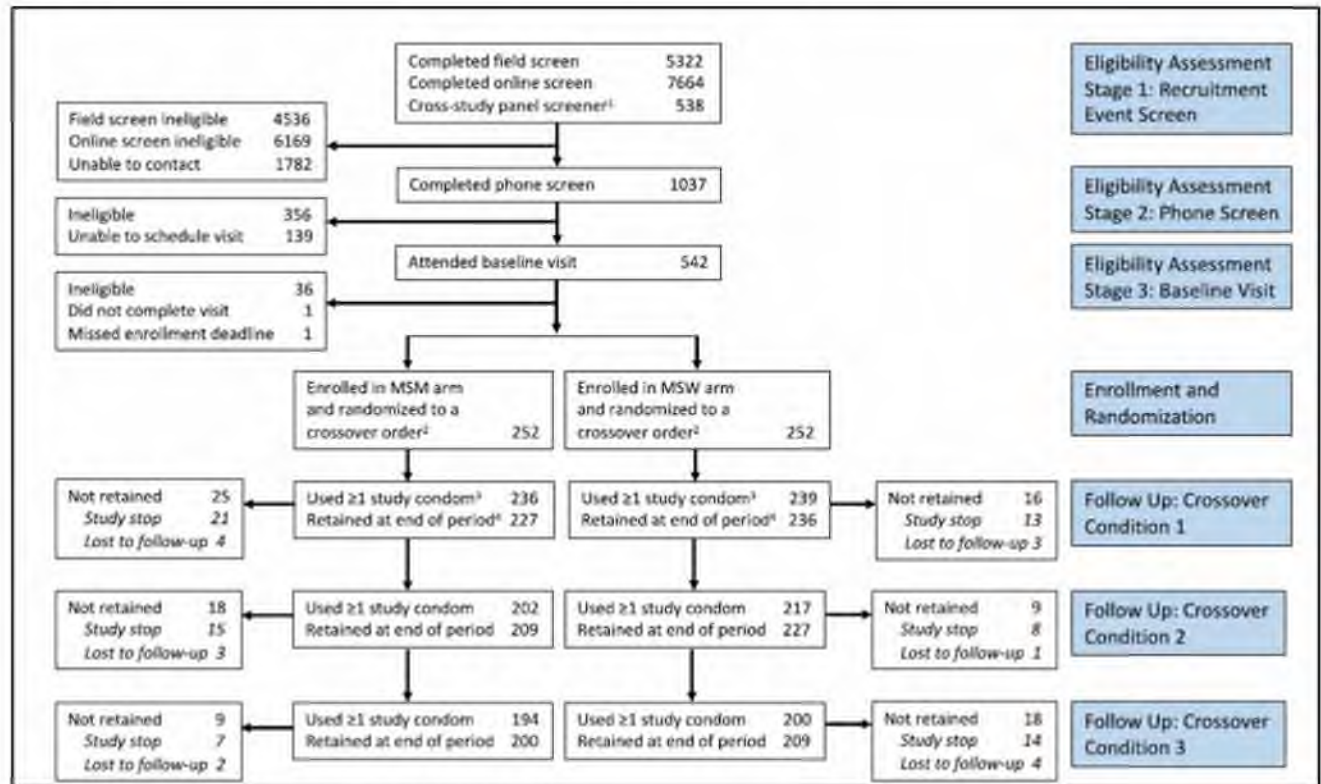


Figure 3: Participant enrollment summary

Demographic and Baseline Data

The study sample was predominantly single (87.3% never married), identified as homosexual for MSM (90.5%) or heterosexual for MSW (97.2%), and diverse (47.8% White non-Hispanic, 12.3% Hispanic, 26.0% African American non-Hispanic, and 13.7% other, non-Hispanic). Nearly three-quarters (74.0%) of participants in both arms rated themselves as “very experienced” using condoms; however, 36.3% of MSM and 38.1% of MSW reported condom slippage, condom breakage or both in the past 6 months.

Effectiveness Analysis

Table 2 provides total clinical failure, slippage, and breakage rates for the different condom types (standard, thin, and fitted) for each study arm using the ITT population.

	Anal Intercourse (n=2351)			Vaginal Intercourse (n=2533)			
	MSM			MSW			
	Slippage	Breakage	Total Clinical Failure	Slippage	Breakage	Total Clinical Failure	Total Failures by Condom Type
n/N, %, (95% CI)							
Fitted	(b)(4)	(b)(4)	5/813 0.62% (0.20%, 1.43%)	(b)(4)	(b)(4)	17/847 2.01% (1.17%, 3.19%)	22/1660 1.33% (0.83%, 2.0%)
Standard			5/750 0.67% (0.22%, 1.55%)			8/839 0.95% (0.41%, 1.87%)	13/1589 0.82% (0.44%, 1.39%)
Thin			6/788 0.76% (0.28%, 1.65%)			23/847 2.72% (1.73%, 4.05%)	29/1635 1.77% (1.19%, 2.54%)
Total Failures by Type of Intercourse			16/2351 0.68% (0.39%, 1.10%)			48/2533 1.89% (1.40%, 2.50%)	

Table 2: Clinical Failure Rates by Condom Type and Study Arm (ITT)

For anal intercourse, there were 16/2,351 (0.68%) condom failures, with failure levels ranging across the three types of condoms from 0.62% to 0.76% (5/813 for the fitted condoms, 5/750 for standard condoms, and 6/788 for thin condoms). There were no significant differences in levels of failure by condom type.

There were a small number of subjects in the MSW arm who used the study condoms outside of the study protocol for anal intercourse. The total clinical failure rate was (b)(4) % (b)(4) in the MSW arm for anal intercourse.

For vaginal intercourse, there were 48/2533 (1.89%) condom failures, with failure levels ranging across the three types of condoms from 0.95% to 2.72% (17/847 for the fitted condoms, 8/839 for standard condoms, and 23/847 for thin condoms).

Overall, the total clinical failure for vaginal and anal intercourse for all condom types (slippage, breakage, or slippage and breakage) was 1.3% (64/4884).

For sex acts in which non-condom compatible lubricant (e.g., oil-based lubricant) was used, failure occurred 2/16 times (12.5%). For sex acts in which condoms were used incorrectly, condoms failed 9/242 times (3.7%).

The results of the per protocol analyses were not substantially different from the ITT results.

The results of the clinical study indicate that slippage, breakage, and total clinical failure for anal intercourse for MSM and vaginal intercourse for MSW for the ONE Male Condom are low.

However, for the limited data available in the pivotal study for anal intercourse in the MSW population (n=7), the total clinical failure rate for anal sex acts is high (100%). To ensure that the clinical study supports the safety and effectiveness of the One Male Condom for anal intercourse in both the MSM and MSW population, the sponsor provided additional clinical information to support that the clinical data from the MSM population can be leveraged to support the MSW population.

The sponsor conducted a literature review to identify studies that evaluated total clinical failure during anal intercourse in the MSW population. In the studies identified, the total condom failure ranged from 15% to 15%. These studies also found that additional confounding factors affect anal intercourse failure rates in the MSW population, e.g., emotional, behavioral, inexperience using condoms, concerns about sexual performance, lubricant use, etc. These factors are not related to the biological sex of the receptive partner, but rather, relate to the individual condom user and how condoms are used. Therefore, the literature does not support that there are biological differences that would contribute to different failure rates for anal intercourse between the MSM and MSW populations. Because sex based biological differences should not affect condom failure rates, the pivotal study results for the MSM population for anal intercourse can be generalized to the MSW population. Accordingly, the information provided in the pivotal clinical study and the literature review support an anal sex indication for the ONE Male Condom that includes both the MSM and MSW population.

The pivotal clinical study data in the MSM population indicate that if a condom compatible lubricant is used and appropriate condom use instructions are provided and followed, the clinical failure for anal intercourse is low. To mitigate the confounding factors identified in the literature studies, the labeling for the ONE Male Condom includes appropriate and complete instructions for use and warnings related to use of lubricant during anal intercourse (e.g., adequate amount of condom compatible lubricant should be used during anal intercourse to help reduce the risk of condom failure).

Safety Analysis

The overall percentage of adverse events (AEs) was 1.92% for both vaginal and anal intercourse. The adverse event rates for anal intercourse using the ONE Male Condom were 0.34% for STI acquisition, 0.34% for condom/lubricant discomfort and 0.04% for partner discomfort. The adverse event rates for vaginal intercourse using the ONE Male Condom were 0.04% for STI acquisition, 0.27% for condom/lubricant discomfort and 0.04% partner UTI.

All AEs were self-reported by the study participants. Regarding STI acquisition, the study did not screen for STIs at baseline, and per the study protocol, the study participants could have sex without the study condoms over the duration of the study. Therefore, the STIs reported in the study may have resulted from unprotected sex prior to the study or during the study.

The AE rates are low, and the AEs observed are commonly found in the real world population using condoms.

Pediatric Extrapolation

For medical devices, the FD&C Act defines patients before their 22nd birthday as pediatric patients. Pediatric patients do not raise additional differences or risks relative to the patient population studied.

LABELING

The ONE Male Condom labeling consists of the primary condom package (individual foil packet), the condom retail package, and the package insert. The labeling includes important information regarding condom use, warnings, precautions, and instructions for use.

The package labeling and directions for use are consistent with “Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300—Class II Special Controls Guidance for Industry and FDA Staff” published in December 2009. While the ONE Male Condom does not fall under 21 CFR 884.5300, the same risks exist between condoms in 21 CFR 884.5300 and this device type, and many of the labeling statements in the special controls document will mitigate those risks for the ONE Male Condom and other devices of the same type.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of an external condom for anal intercourse or vaginal intercourse and the measures necessary to mitigate these risks.

Identified Risks to Health	Mitigation Measures
Transmission of Sexually Transmitted Infection	Acute failure modes clinical study Non-clinical performance testing Shelf life testing Labeling
Pregnancy	Acute failure modes clinical study Non-clinical performance testing Shelf life testing Labeling

Adverse tissue reaction	Biocompatibility evaluation Labeling
Mechanical injury leading to ulceration, laceration, trauma	Acute failure modes clinical study Non-clinical performance testing Shelf life testing Labeling
Use error/Improper device use leading to the risks above	Acute failure modes clinical study Labeling

SPECIAL CONTROLS

In combination with general controls of the Food Drug & Cosmetic Act, an external condom for anal intercourse or vaginal intercourse is subject to the following special controls:

- (1) Clinical performance data must demonstrate the total rate of clinical failure and rate of individual failure modes of the device based on an acute failure modes study.
- (2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The data must include an assessment of mechanical and material integrity, including an evaluation of device failure modes. For devices made of materials other than natural rubber latex, viral penetration testing must be conducted to evaluate barrier effectiveness to sexually transmitted infections.
- (3) The device must be demonstrated to be biocompatible.
- (4) Performance data must support the shelf life of the device by demonstrating device functionality and package integrity over the identified shelf life.
- (5) Labeling must include:
 - a. If indicated for vaginal intercourse, a contraceptive effectiveness table comparing typical use and perfect use pregnancy rates with the device to other available methods of birth control;
 - b. Statement regarding compatibility with additional lubricant types;
 - c. Statement regarding the adverse events associated with the device, including transmission of infection, pregnancy, adverse tissue reaction, mechanical injury, or improper device use;
 - d. Expiration date;
 - e. The following information, warnings and precautions:

- i. The sexually transmitted infections (STIs) for which the device is most protective, the degree of protection the device provides against specific types of STIs, and the STIs the device does not protect against;
- ii. A statement that the device does not completely eliminate the risks of pregnancy and sexually transmitted infections and that risk can be decreased with correct and consistent use;
- iii. A warning regarding the risk of device failure during anal intercourse if adequate lubricant is not used;
- iv. A warning stating that the device cannot be used multiple times and is limited to one sex act;
- v. A precaution stating not to use the device if the user is at risk for material related allergic reactions.

BENEFIT-RISK DETERMINATION

The benefits and risks of the device are based on data collected in the pivotal clinical study described above.

The risks of the device are based on AE data collected in the pivotal clinical study. The overall percentage for AEs is low, with a reported rate of (b)(4)% for both vaginal and anal intercourse. The adverse event rates for anal intercourse using the ONE Male Condom were (b)(4)% for STI acquisition, (b)(4)% for condom/lubricant discomfort and (b)(4)% for partner discomfort. The adverse event rates for vaginal intercourse using the ONE Male Condom were (b)(4)% STI acquisition, (b)(4)% condom/lubricant discomfort and (b)(4)% partner UTI. There were no reported pregnancies.

In the pivotal study, there was a low rate of total clinical failure (0.68% (16/2351)) for the ONE Male Condom when used for anal sex in the MSM population. There was also a low rate of total clinical failure (1.89% (48/2533)) for the ONE Male Condom when used for vaginal sex in the MSW population. The literature does not support that there are biological differences that would contribute to different failure rates for anal intercourse between the MSM and MSW populations. Based on these results, the benefits of the ONE Male Condom are protection against STIs and unplanned pregnancy. Since unprotected anal intercourse carries the greatest sexual exposure risk of transmission of HIV and other STIs, a condom indicated specifically for anal intercourse will be beneficial for both MSM and MSW.

PATIENT PERSPECTIVES

The sponsor provided a brief survey among a sample of MSM. Data were collected from September 2015 through April 2016 through the American Men's Internet Survey (AMIS), an annual Internet survey of MSM in the United States. The survey explored willingness to use condoms under a hypothetical condition of an FDA condom indicated specifically for anal intercourse. In a sample of 2,079 MSM, 69% (95% Confidence Interval: 67%, 71%) reported that they would be more likely to use condoms more frequently if the condoms were indicated for specifically for anal intercourse.

BENEFIT/RISK CONCLUSION

In conclusion, given the available information above, for the following indication statement:

The ONE Male Condom is used for contraception to help reduce the risk of pregnancy during vaginal intercourse and for prophylactic purposes to help reduce the transmission of sexually transmitted infections (STIs) during vaginal or anal intercourse. The ONE Male Condom should be used with a condom compatible lubricant when used for anal intercourse.

The probable benefits outweigh the probable risks for the ONE Male Condom. The device provides benefits, and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the ONE Male Condom is granted and the device is classified as follows:

Product Code: QRZ

Device Type: External condom for anal intercourse or vaginal intercourse

Class: Class II

Regulation Number: 21 CFR 884.5305