510k Summary: FuckWater Personal Lubricant

Submitter Information

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Device Information

Device Name: FuckWater
Common or Usual Name: Personal lubricant
Classification: 21 CFR 884.5300; condom
Product Code: NUC; lubricant, personal
Device Class: II

Predicate: Glycerin and Paraben Free Astroglide, K072647

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

Intended Use / Indications for Use

FuckWater is a water-based personal lubricant for penile and/or vaginal and/or rectal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Device Description

FuckWater is a non-sterile, home-use, water-based, personal lubricant. It is packaged in 2oz, 4oz, 8oz and 16oz bottles. The device is intended to be applied to the penis, vagina or rectum to reduce friction during sexual activity. The device is compatible with natural rubber latex and polyisoprene condoms. The device is not compatible with polyurethane condoms. The device has the following specifications:

Parameter	Specification
Appearance	Viscous, Semi-Opaque Fluid
Color	Off-White
Odor	Light Medicinal
pH	7.2 - 7.6
Osmolality	2,300-3,400 mOsm/kg
Viscosity	20,000 - 26,000 cP
Antimicrobial effectiveness (USP <51>)	Bacteria: Not less than 2.0 log reduction from the initial count at 14 days, and no increase from the 14 days' count at 28 days Yeast and Mold: No increase from the initial calculated count at 14 and 28 days
Total Aerobic Microbial Count (USP <61>, <62>)	< 10 cfu/g
Total Yeast and Mold Count (USP <61>, <62>)	< 10 cfu/g
Absence of Pathogenic Organisms (USP <61>, <62>)	Negative *(P. aeruginosa, S. aureus, Salmonella, E. coli, Clostridia, C. albicans, Bile-Tolerant Gram-Negative Bacteria).*

Comparison to Predicate Device

FuckWater is substantially equivalent to the predicate device listed below with respect to intended use/indications for use, principles of operation and technological characteristics.

Substantial Equivalence Table

Attribute	**Fuck-Water (Subject Device)**	**Glycerin and Paraben Free Astroglide (Predicate)**	**Equivalence**
510(k)	K171730	K072647	N/A
Product Code	NUC	NUC	Same

Indications for Use	FuckWater is a water-based personal lubricant, for penile, vaginal and/or rectal application, intended to moisturize and lubricate, enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	Glycerin and Paraben Free Astroglide® is a personal lubricant, for penile, anal, or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with latex condoms.	Similar; minor differences do not change the intended use and do not raise different questions of safety and effectiveness.
Condom Compatibility	Natural Rubber Latex Polyisoprene	Natural Rubber Latex	Different; differences in condom compatibility do not raise different questions of safety and effectiveness.
Over-The-Counter Use	Yes	Yes	Same
Ingredients	Water, Propylene Glycol, Isopropyl Palmitate, Dimethicone, Hydroxyethyl Cellulose, Polysorbate 20, Sorbitan Stearate, Cetearyl Alcohol, Glyceryl Stearate, Sodium Benzoate, Gluconolactone	Water, Butylene Glycol, Xylitol, Propylene Glycol, Polyquaternium 15	Different; differences in formulation do not raise different questions of safety and effectiveness.
Biocompatibility Tested	Yes	Yes	Same
Sterile	No	No	Same
Microbial Quality and Antimicrobial Effectiveness Tested	Yes	Yes	Same

As noted in the table above, the differences between the subject and predicate devices include the indications for use, condom compatibility and ingredients. These differences do not alter the intended use or the fundamental technology of the subject device as compared to the predicate, and do not raise different questions of safety or effectiveness. The technological differences between the subject device and predicate were evaluated through performance testing as described in the section below.

Summary of Non-Clinical Performance Data

Biocompatibility

The subject device is intended to come into direct contact with the mucosa of patients for a limited (< 24hr) duration. Therefore, biocompatibility testing was conducted to evaluate vaginal and rectal irritation, systemic toxicity, hypersensitivity and cytotoxicity in accordance with ISO 10993 as described below.

Cytotoxicity
The purpose of this test was to examine the test article under evaluation for cytotoxic potential. This test was performed per ISO 10993-5:2009. Based on qualitative evaluation of the mouse fibroblast cells exposed to the tested test article, the test article was demonstrated to be non-cytotoxic.

Hypersensitivity
The purpose of this test was to determine to what extent a test article has the potential to act as a contact sensitizer in guinea pigs. The assay was conducted according to the methods detailed in the ISO 10993-10:2010, Guinea Pig Maximization Sensitization. Results from treated animals support that the test article is non-sensitizing. Under similar treatment conditions, all positive control animals used in the historical positive control study exhibited a strong sensitization response to the challenge dose compared to that of the control animals. The results from the historical positive control study demonstrate that the guinea pigs in the study reacted as expected when exposed to a known sensitizer (i.e., DNCB) and the results validate the sensitivity of this test.

Vaginal Mucosal Irritation
The purpose of this test was to assess the potential of the test material to produce irritation of the vaginal mucosal tissue in New Zealand White rabbits. This test was performed according to ISO 10993-10:2010, Vaginal Irritation Test. Based on the Irritation Index, the test article was considered a non-irritant to the vaginal mucosa.

Rectal Irritation
The purpose of this test was to assess the potential of the test material to produce irritation of the rectal mucosal tissue in New Zealand White rabbits. This test was performed according to ISO 10993-10:2010, Rectal Irritation Test. Based on the Irritation Index, the test article was considered a non-irritant to the rectal mucosa.

Acute Systemic Toxicity
The purpose of this test was to evaluate systemic responses to the test article following injection into mice. This test was conducted according to ISO 10993-11:2006, Acute Systemic Toxicity. Testing demonstrated that the subject device is not acutely toxic.

Bench Performance Testing

The following non-clinical testing was conducted: Condom compatibility in accordance with ASTM D7661:10 and age testing (ASTM F1980-16) to justify claims of 522 days shelf-life.

Shelf Life
Shelf life for the subject device is claimed to be 522 days. Accelerated aging testing was conducted per ASTM F1980-16, which demonstrated that the device met specifications for the proposed shelf-life.

Condom Compatibility

Condom compatibility was conducted in accordance with ASTM D7661-10 – Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex. The subject device was found to be compatible with male natural rubber latex and polyisoprene condoms and incompatible with male polyurethane condoms.

Summary of Clinical Performance Data

No clinical data were submitted to support substantial equivalence.

Conclusion

The subject device has very similar indications for use to the predicate. Minor differences in the indications statements do not alter the intended use of the subject device. The subject device and the predicate have the same basic technological characteristics. Minor differences in technology do not alter the intended use or fundamental technology, and do not raise different questions of safety and effectiveness. The technological differences between the subject and predicate device were evaluated through performance testing, including biocompatibility, condom compatibility, and shelf-life. The results from performance testing support that the subject device is as safe and effective as the predicate. Therefore, the subject device is substantially equivalent to the predicate device.