510(k) Summary – K173504

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Proprietary Name: K-Y® Silicone

Trade Name: K-Y® Silicone

Common Name: Personal Lubricant

Classification Name: Condom (21 CFR §884.5300)

Product Code: NUC (lubricant, personal)

Regulatory Class: II

Predicate Device(s):

Durex Silicone (K143532)

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

Description of the Device:

K-Y® Silicone is a non-sterile, odorless, and anhydrous personal lubricant that provides personal lubrication during intimate sexual activity and is compatible with condoms made of natural rubber latex, polyurethane and polyisoprene. This product is composed of 100% Dimethicone. The product is packaged in a 50mL (1.69 FL oz.) HDPE bottle with a polypropylene pump. K-Y® Silicone is identical in formulation and specifications to the predicate device (Durex Silicone, K143532).

Specifications for the K-Y® Silicone personal lubricant are shown in the table below:

Property	**Specification**
Color	Colorless
Odor	Odorless
Viscosity	80-110 cps
TAMC (EP 2.6.12 harmonized to USP <61>)	<10 cfu/g
TYMC (EP 2.6.12 harmonized to USP <61>)	Absent
Absence of Pathogenic Organisms (*Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus)* (EP 2.6.13 harmonized to USP <62>)	Absent

Indication for Use:

K-Y® Silicone is indicated for penile, vaginal and/or anal 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, polyisoprene, and polyurethane condoms.

Predicate Device Comparison:

Intended Use:

The indications for use for the subject and predicate devices are shown in the table below:

K-Y® Silicone K173504	**Durex Silicone K143532**
K-Y® Silicone is indicated for penile, vaginal and/or anal 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, polyisoprene, and polyurethane condoms.	Durex Silicone is indicated for penile and/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 natural rubber latex, polyisoprene, and polyurethane condoms.

The subject and predicate device have similar indications for use. However, the indication for the subject device has been expanded from the current penile and vaginal use to also include anal use. This change does not represent a new intended use as the intended use of this device is the same as the predicate device, i.e., lubrication of an orifice during intimate sexual activity.

Additionally, FDA has cleared otherpersonal lubricants with comparable indications including penile, vaginal, and anal use.

Technological Characteristics:

The technological characteristics of the K-Y® Silicone personal lubricant are identical to the predicate device as both devices are made from the same material, have the same packaging, and have the same specifications.

Summary of Performance Data

This submission relies on the performance testing provided in the predicate submission for the Durex Silicone personal lubricant (K143532) as the subject device is identical to the predicate device. Data from the predicate submission used to support the subject device is summarized below:

Biocompatibility: Testing was conducted in accordance with ISO 10993-1:2009. The following endpoints were assessed in the testing conducted:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Irritation (ISO 10993-10:2010)
- Systemic Toxicity (ISO 10993-11:2011

The results of this testing demonstrated that the subject lubricant is biocompatible.

Condom Compatibility: Testing was done in accordance with ASTM method D7661-10 on condoms made of natural rubber latex, polyisoprene, and polyurethane. The results of testing showed compatibility of the lubricant with natural rubber latex, polyisoprene, and polyurethane condoms.

Shelf-Life: K-Y® Silicone is a non-sterile personal lubricant with a 24 month shelf-life based on the results of accelerated a and real-time stability studies. Testing showed that devices were able to meet the device specifications shown in the Device Description section of this summary over the 24-month shelf-life period.

Conclusion

As K-Y® Silicone is identical to the predicate Durex Silicone personal lubricant, the performance data described above demonstrates that the K-Y® Silicone personal lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.