



Food and Drug Administration  
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June 9, 2017

Biotech Lubricants Ltd  
% Karen Cornelius  
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United Kingdom

Re: K162569  
Trade/Device Name: YES® oil-based Personal Lubricant, YES® water-based Personal Lubricant, YES® Vaginal Moisturizer  
Regulation Number: 21 CFR 884.5300  
Regulation Name: Condom  
Regulatory Class: II  
Product Code: NUC  
Dated: May 9, 2017  
Received: May 11, 2017

Dear Karen Cornelius:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

  
**Benjamin R. Fisher -S**

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K162569

Device Name

YES® oil-based Personal Lubricant, YES® water-based Personal Lubricant, YES® Vaginal Moisturizer

Indications for Use (Describe)

Device Name: YES® oil-based Personal Lubricant

Indications for Use:

A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® oil-based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Device Name: YES® water-based Personal Lubricant

Indications for Use:

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

Device Name: YES® Vaginal Moisturizer

Indications for Use:

A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® Vaginal Moisturizer is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

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**

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**Date Prepared:** June 9, 2017

**Device Proprietary Names:** YES<sup>®</sup> oil-based Personal Lubricant  
 YES<sup>®</sup> water-based Personal Lubricant  
 YES<sup>®</sup> Vaginal Moisturizer

**Device Common Name:** Personal Lubricant

**Classification:** Condom (21 CFR 884.5300)

**Regulatory Class:** II

**Product Code:** NUC (lubricant, personal)

**Predicate Device:** K124044 Aloe Cadabra Personal Lubricant (Seven Oaks Ranch, Inc.)  
 K122477 Lifestyles Luxe Premium Personal Lubricant (Ansell Healthcare Products LLC)

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

**Device Description:**

YES<sup>®</sup> oil-based Personal Lubricant: This non-sterile and oil-based personal lubricant consists primarily of Sunflower oil and Shea butter, and is not compatible with condoms. It is neither a contraceptive nor a spermicide. The formulation is a cream-colored thick paste that melts at body temperature. The product is packaged in a high density polyethylene (HDPE) tube with a flip-top cap. The specifications for the YES<sup>®</sup> oil-based Personal Lubricant are shown below:

Parameter	Specification
Color	Opaque paste
Odor	Slight beeswax and/or cocoa odor
Viscosity	N/A: measuring viscosity is not feasible, since changes in phase during measurement lead to differences in viscosity readings
Total yeast/mold count	<10 cfu/g (USP<61>)
Total aerobic mesophilic count	<100 cfu/g (USP<61>)
Absence of Pathogenic bacteria: <i>Staphylococcus aureus, Candida</i>	Absent in 1g (USP<62>)

<i>albicans, and gram negative bacteria (e.g., Pseudomonas aeruginosa)</i>	
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**YES® water-based Personal Lubricant:** This non-sterile and water-based personal lubricant contains Aloe vera and other components, and is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. It is neither a contraceptive nor a spermicide. The formulation is a lightly opaque, non-greasy liquid gel. The product is packaged in a HDPE tube with a flip-top cap, and a HDPE single-use applicator. The specifications for the YES® water-based Personal Lubricant are shown below:

Parameter	Specification
Color	Opaque gel
Odor	Slight-mild, delicate linseed / leather note
Viscosity	2,000 – 20,000 cP
pH	3.70 - 4.50
Osmolality	100 - 400 mOsm/kg
Antimicrobial Effectiveness	At least 2.0 log reduction from the initial count at 14 days; no increase from the 14 days count at 28 days; no increase from the initial calculated count at 14 and 28 days (USP <51>)
Total yeast/mold count	<10 cfu/g (USP<61>)
Total aerobic mesophilic count	<100 cfu/g (USP<61>)
<i>Absence of Pathogenic bacteria: Staphylococcus aureus, Candida albicans, and gram negative bacteria (e.g., Pseudomonas aeruginosa)</i>	Absent in 1g (USP<62>)

**YES® Vaginal Moisturizer:** This non-sterile and water-based personal lubricant contains Aloe vera and other components, and is compatible with natural rubber latex, and polyisoprene condoms. This product is not compatible with polyurethane condoms. It is neither a contraceptive nor a spermicide. The formulation is a lightly opaque, non-greasy liquid gel. The product is packaged in a HDPE tube with a flip-top cap, and a HDPE single-use applicator. The specifications for the YES® Vaginal Moisturizer are shown below:

Parameter	Specification
Color	Opaque gel
Odor	Slight-mild, delicate linseed / leather
Viscosity	2,000 – 20,000 cP
pH	3.50-4.50
Osmolality	250-400 mOsm/kg
Antimicrobial Effectiveness	At least 2.0 log reduction from the initial count at 14 days; no increase from the 14 days count at 28 days; no increase from the initial calculated count at 14 and 28 days (USP <51>)
Total yeast/mold count	<10 cfu/g (USP<61>)
Total aerobic mesophilic count	<100 cfu/g (USP<61>)
<i>Absence of Pathogenic bacteria:</i>	Absent in 1g (USP<62>)

<i>Staphylococcus aureus, Candida albicans, and gram negative bacteria (e.g., Pseudomonas aeruginosa)</i>	
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**Indications for Use:**

YES<sup>®</sup> oil-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES<sup>®</sup> oil-based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

YES<sup>®</sup> water-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES<sup>®</sup> water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

YES<sup>®</sup> Vaginal Moisturizer: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES<sup>®</sup> Vaginal Moisturizer is compatible with natural rubber latex, and polyisoprene condoms. This product is not compatible with polyurethane condoms.

**Comparison of Intended Use and Technological Characteristics of Subject and Predicate Devices:**

YES <sup>®</sup> oil-based Personal Lubricant			Comparison
510(k) #	K162569	K122477	
Device Name	YES <sup>®</sup> oil-based personal lubricant	LifeStyles Luxe Premium Personal Lubricant	
Manufacturer	Bio-tech Lubricants Ltd	Ansell Healthcare Products, LLC	
Classification	884.5300	884.5300	
Product code	NUC	NUC	
Description	Personal Lubricant	Personal Lubricant	Same
Indications for use	A personal lubricant, for vaginal and penile 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 not compatible with natural rubber latex, polyurethane or polyisoprene condoms.	LifeStyles Luxe Premium Personal Lubricant Is a personal lubricant, 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, polyurethane, and polyisoprene condoms.	Different: The subject and predicate devices indication for use statements differ in regards to compatibility with condoms. Differences noted do not represent a new intended use.
Oil-based lubricant	YES	YES	Same: the subject and predicate devices are both oil-based lubricants; however, the specific oils in the formulation are

YES <sup>®</sup> oil-based Personal Lubricant			Comparison
			different. This does not raise different questions of S & E (e.g. biocompatibility).
Ingredients	Sunflower seed oil, Shea butter, Sweet almond oil, Bees wax, Cocoa seed butter, Vitamin E	Not known	Different: The difference in ingredients do not raise different questions of S & E.
Biocompatible	YES	YES	Same
Non-sterile	YES	YES	Same
Contains preservatives	NO	NO	Same
Microbial limits (TAMC, TYMC, and absence of pathogenic bacteria)	See product specifications table (USP <61> & <62>)	Meets the requirements of USP <61> & <62>	Different: the microbial limits of the predicate are not known; however this does not raise different questions of S & E as the microbial limits specifications are within the accepted ranges for these types of devices.
Condom Compatibility	Not compatible with natural rubber latex, polyurethane, or polyisoprene condoms.	Compatible with natural rubber latex, polyurethane, and polyisoprene condoms.	Different: The condom compatibility for the subject and predicate devices are different; However, this difference does not represent a new intended use.

As noted in the table above the subject and predicate devices indications are similar in that they are both used to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. However, they do differ in regards to condom compatibility as the subject device is not compatible with condoms, while the predicate is condom compatible. Differences in condom compatibility between the subject and predicate devices do not represent a new intended use. In regards to technology, the subject and predicate devices are similar in that they are both non-sterile and are oil-based. Differences do exist as described in the table above (e.g., product formulations, specifications for microbial limits, condom compatibility, etc.). The differences identified do not raise different questions of safety and effectiveness as discussed in the table above

YES <sup>®</sup> water-based Personal Lubricant			Comparison
510(k) #	K162569	K124044	
Device name	YES <sup>®</sup> water-based Personal Lubricant	Aloe Cadabra Personal lubricant	
Manufacturer	Bio-tech Lubricants Ltd	Seven Oaks Ranch, Inc.	
Classification	884.5300	884.5300	
Product code	NUC	NUC	
Description	Personal Lubricant	Personal Lubricant	Same
Indications for use	A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to	Aloe Cadabra Lubricant and Aloe Cadabra Flavored/Scented Lubricants are personal lubricants for	Same: The subject and predicate devices have the same indication for use, and therefore have the

<b>YES® water-based Personal Lubricant</b>			<b>Comparison</b>
	enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	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 and polyisoprene condoms. This product is not compatible with polyurethane condoms.	same intended use.
Water-based lubricant	YES	YES	Same
Ingredients	Water, Aloe vera, Flax seed extract, Guar gum, Locust bean gum, Xanthan gum, Sodium chloride, Potassium sorbate, Citric acid, Phenoxyethanol	Aloe vera	Different: The difference in ingredients do not raise different questions of S & E.
Biocompatible	YES	YES	Same
Non-sterile	YES	YES	Same
Contains preservatives	YES	YES	Same
Microbial limits (TAMC, TYMC, and absence of pathogenic bacteria)	See product specifications table (USP <61> & <62>)	Not known	Different: the microbial limits of the predicate are not known; however this does not raise different questions of S & E as these specifications are within the accepted range for these types of devices.
Viscosity	2,000 – 20,000 cP	Not known	Different: the viscosity of the predicate is not known. This does not raise different questions of S & E as the viscosity specification is within the accepted range for these types of devices.
pH	3.70 - 4.50	Not known	Different: the pH of the predicate is not known. This does not raise different questions of S & E as the pH specification is within the accepted range for these types of devices.
Osmolality	100 - 400 mOsm/kg	Not known	Different: the osmolality of the predicate is not known. This does not raise different questions of S & E as the osmolality specification is within the accepted range for these types of devices.



YES® water-based Personal Lubricant			Comparison
Condom Compatibility	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms.	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms.	Same

As noted in the table above the subject and predicate devices have the same indication for use and intended use. In addition, the subject and predicate devices are similar in that they are both non-sterile, compatible with the same types of condoms, contain Aloe vera, and are water-based. Differences do exist as described in the table above (e.g., product formulations, specifications for microbial limits, viscosity, etc.). The differences identified do not raise different questions of safety and effectiveness as discussed in the table above.

YES® Vaginal Moisturizer			Comparison
510(k) #	K162569	K124044	
Device Name	YES® VM (Vaginal Moisturizer)	Aloe Cadabra Personal lubricant	
Manufacturer	Bio-tech Lubricants Ltd	Seven Oaks Ranch, Inc.	
Classification	884.5300	884.5300	
Product code	NUC	NUC	
Description	Personal Lubricant	Personal Lubricant	Same
Indications for use	A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® Vaginal Moisturizer is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.	Aloe Cadabra Lubricant and Aloe Cadabra Flavored/Scented Lubricants are personal lubricants 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 and polyisoprene condoms. This product is not compatible with polyurethane condoms.	Same: The subject and predicate devices have the same indication for use, and therefore have the same intended use.
Water-based lubricant	YES	YES	Same
Ingredients	Water, Aloe vera, Flax seed extract, Guar gum, Locust bean gum, Xanthan gum, Sodium chloride, Potassium sorbate, Citric acid, Phenoxyethanol	Aloe vera	Different: The difference in ingredients do not raise different questions of S & E.
Biocompatible	YES	YES	Same
Non-sterile	YES	YES	Same
Contains preservatives	YES	YES	Same
Microbial Limits	See product specifications	Not known	Different: the microbial

YES <sup>®</sup> Vaginal Moisturizer			Comparison
(TAMC, TYMC, and absence of pathogenic bacteria)	table (USP <61> & <62>)		limits of the predicate are not known; however this does not raise different questions of S & E as these specifications are within the accepted range for these types of devices.
Viscosity	2,000 – 20,000 cP	Not known	Different: the viscosity of the predicate is not known. This does not raise different questions of S & E as the viscosity specification is within the accepted range for these types of devices
pH	3.50-4.50	Not known	Different: the pH of the predicate is not known. This does not raise different questions of S & E as the pH specification is within the accepted range for these types of devices.
Osmolality	250-400 mOsm/kg	Not known	Different: the osmolality of the predicate is not known. This does not raise different questions of S & E as the osmolality specification is within the accepted range for these types of devices.
Condom Compatibility	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms.	Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms.	Same

As noted in the table above the subject and predicate devices have the same indication for use and intended use. In addition, the subject and predicate devices are similar in that they are both non-sterile, compatible with the same types of condoms, contain Aloe vera, and are water-based. Differences do exist as described in the table above (e.g., product formulations, specifications for microbial limits, viscosity, etc.). The differences identified do not raise different questions of safety and effectiveness as discussed in the table above.

**Performance Testing:**

**Biocompatibility:**

Testing was conducted to assess the biocompatibility of the YES<sup>®</sup> oil-based Personal Lubricant, YES<sup>®</sup> water-based Personal Lubricant and YES<sup>®</sup> Vaginal Moisturizer. Testing included assessments for Cytotoxicity (ISO 10993-5:2009(R)2014), Vaginal Irritation (ISO 10993-10:2010(R)2014), Sensitization (ISO 10993-10:2010(R)2014), and Acute Systemic Toxicity (ISO 10993-11:2006).

The results of testing demonstrated that they are non-cytotoxic, non-irritating, non-sensitizing and non-systemically toxic.

Condom Compatibility:

YES<sup>®</sup> oil-based Personal Lubricant: Condom compatibility testing was performed for polyurethane condoms per ASTM D7661-10. The results indicate that the device is not compatible with polyurethane condoms. Additionally, compatibility testing was not performed for natural rubber latex or polyisoprene condoms; therefore, the device is not compatible with natural rubber latex or polyisoprene condoms.

YES<sup>®</sup> Vaginal Moisturizer and YES<sup>®</sup> water-based Personal Lubricant: Condom compatibility testing was performed per ASTM D7661-10. The results indicated that the devices are compatible with natural rubber latex and polyisoprene condoms, but are not compatible with polyurethane condoms.

Shelf Life and Microbial Limits:

YES<sup>®</sup> oil-based Personal Lubricant, YES<sup>®</sup> water-based Personal Lubricant, and YES<sup>®</sup> Vaginal Moisturizer have a 9-month shelf life. The results of shelf-life testing demonstrated that the subject lubricants met all device specifications as shown in the Device Description section for the duration of the 9-month shelf-life.

**Conclusion:**

YES<sup>®</sup> oil-based Personal Lubricant, YES<sup>®</sup> water-based Personal Lubricant, and YES<sup>®</sup> Vaginal Moisturizer have the same intended use and similar technological characteristics as the predicate devices. The results of the performance testing conducted on the subject devices demonstrate that they are as safe and effective as the predicate devices and support substantial equivalence.