February 6, 2020

Bio-Tech Lubricants Ltd
Karen Cornelius
Regulatory Affairs Manager
C/O The Timber Barn, Selborne Road
Greatham, Liss, Hampshire GU33 6HG
UNITED KINGDOM

Re: K191411
Trade/Device Name: AH! YES OB COCO Personal Lubricant
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: December 23, 019
Received: December 23, 2019

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. 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,

Monica D. Garcia, Ph.D.
Acting 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)*
K191411

Device Name
AH!YES OB COCO Personal Lubricant

Indications for Use *(Describe)*
AH! YES® OB COCO: 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. AH! YES® OB COCO is not compatible with natural rubber latex, polyurethane or polyisoprene 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.**

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.***

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# 510 (k) Summary – K191411

## 1. Submitter Information

Applicant: Bio-Tech Lubricants Limited
Address: Epsilon House, Enterprise Road,
Southampton Science Park,
Southampton, SO6 7NS
United Kingdom
Phone: +44 (0) 3450 94 11 41
Email: sarah@ahyes.org

## 2. Correspondent Information

Contact: Karen Cornelius
Bio-Tech Lubricants Limited,
Address: C/O The Timber Barn,
Selborne Road, Greatham,
Hampshire.
GU33 6HG
United Kingdom
Phone: +44 (0) 3450 94 11 41
Email: Karen@yesyesyes.org

## 3. Date prepared: February 04, 2020

## 4. Device Information

| | |
|---|---|
| Device Name: | AH! YES OB COCO Personal Lubricant |
| Common Name: | Personal Lubricant |
| Regulation Number: | 21 CFR 884.5300 |
| Regulation Name: | Condom |
| Regulatory Class: | Class II |
| Product Code: | NUC (lubricant, personal) |

## 5. Predicate Device Information

| | |
|---|---|
| Device Name: | YES Oil-based Personal Lubricant |
| 510(k) Number: | K162569 |
| Manufacturer: | Bio-Tech Lubricants Limited |
| Regulatory Class: | Class II |
| Product Code: | NUC (lubricant, personal) |

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

## 6. Device Description

AH! YES OB COCO is a non-sterile, plant-oil based personal lubricant that consists primarily of sunflower oil and fractionated coconut oil and is not compatible with condoms. It is neither a contraceptive nor a spermicide. The formulation is an opaque paste that melts at body temperature. The product is packaged in a polyethylene single use applicator.

The device specifications for AH! YES OB COCO are listed in the table below:

**Table 1: Device Specifications for "AH! YES OB COCO personal lubricant"**

| **Property** | **Specification** |
|---|---|
| Appearance | Opaque paste below melt point, oily pale yellow liquid above melt point |
| Color | Pale yellow |
| Odor | Slight odor, strengthening with age |
| Specific Gravity | 0.85 - 1.0 |
| Total aerobic microbial count (TAMC) per USP <61> | Less than 100 cfu/g |
| Total yeast and mold count (TYMC) per USP <61> | Less than 10 cfu/g |
| **Presence of Pathogens per USP <62>** | **Specification** |
| *Staphylococcus aureus* | Absent |
| *Candida albicans* | Absent |
| *Gram negative bacteria (e.g. Pseudomonas aeruginosa* | Absent |

## 7. Indications for Use

AH!YES® OB COCO: 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. AH! YES® OB COCO is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

## 8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below lists the a comparison of the indications for use and technological characteristics of the subject and predicate device.

**Table 2: Comparator Table for Subject Device – The AH!YES OB COCO Personal Lubricant and Predicate Device YES Oil-based Personal Lubricant**

| | **AH!YES OB COCO Personal Lubricant (K191411)** | **YES Oil-based Personal Lubricant (K162569)** |
|---|---|---|
| Device Classification Name | Lubricant, Personal | Lubricant, Personal |
| Product Code | NUC | NUC |
| Indications for Use | AH!YES® OB COCO: 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. AH! YES OB COCO is not compatible with natural rubber latex, polyurethane or polyisoprene condoms | YES OB personal lubricant is 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. |

| | | |
|---|---|---|
| Water soluble | No | No |
| Contains water | No | No |
| Oil based lubricant | Yes | Yes |
| Primary ingredients | Sunflower seed oil, Coconut oil, Jojoba seed oil, Dermofeel Viscolid, Grapeseed Oil, Vitamin E | Sunflower seed oil, Shea butter, Sweet almond oil, Bees wax, Cocoa seed butter, Vitamin E |
| Sterile | No | No |
| Condom Compatibility | Not compatible with NRL, polyisoprene or polyurethane condoms | Not compatible with NRL, polyisoprene or polyurethane condoms |
| Biocompatibility Tested | Yes | Yes |
| Total Microbial Count | Less than 100 cfu/g | Less than 10 cfu/g |
| Fungal/Yeast/Mold Limits | Less than 10 cfu/g | Less than 10 cfu/g |
| Absence of Pathogenic Organisms | Absent | Absent |
| Packaging materials | Plastic / Polyethylene | Plastic / Polyethylene |

The subject and predicate device have similar indications for use and have the same intended use. The subject and predicate device have different technological characteristics, including different formulations and specifications. The different technological characteristics of the subject device do not raise different types of safety and effectiveness questions.

**9. Summary of Non-Clinical Performance Testing**

**Biocompatibility**

Biocompatibility studies, including Acute Systemic Toxicity, Vaginal Irritation Testing, Cytotoxicity and Sensitization testing were performed in accordance with the 2016 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"* and ISO 10993- 1:2009 as follows:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Vaginal Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993-11:2006)

The results of this testing demonstrated that the AH!YES OB COCO personal lubricant is non-cytotoxic, non-irritating, non-sensitizing, and non-systemically toxic.

**Shelf-Life**

The subject devices are non-sterile personal lubricants with a 24-month shelf-life in accordance with the results of accelerated aging studies per ASTM F1980-16 and real time storage. All device specifications listed in **Table 1** were evaluated for shelf-life. The subject device met the device specifications at all time points.

**Condom Compatibility**

The compatibility of the subject device with natural rubber latex, polyisoprene and polyurethane condoms was evaluated in accordance with ASTM D7661-10 Standard Test Method for Determining

Compatibility of Personal Lubricants with Natural Rubber Latex Condoms. The results of this test demonstrate that the device is not compatible with condoms.

**10. Conclusion**

The results of the performance testing described above demonstrate that the AH!YES OB COCO Personal Lubricant is as safe and effective as the predicate device and supports a determination of substantial equivalence.