September 22, 2017

NEO COSMETIQUE
% Gayle Lyne
Official Correspondent
Technic, Inc.
47 Molter Avenue
Cranston, R I 02910

Re: K163674
Trade/Device Name: Exsens Personal Lubricant - Pure Aqua / Exsens Personal
Lubricant - Aloe Vera / Exsens Personal Lubricant - Fresh Mint /
Exsens Personal Lubricant - Candy Apple / Exsens Personal
Lubricant - Raspberry
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: August 10, 2017
Received: August 21, 2017

Dear Gayle Lyne:

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,

Charles Viviano -S

For 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

Device Name
Exsens Personal Lubricant - Pure Aqua / Exsens Personal Lubricant - Aloe Vera / Exsens Personal Lubricant - Fresh Mint / Exsens Personal Lubricant - Candy Apple / Exsens Personal Lubricant - Raspberry

Indications for Use (Describe)
Intended 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. These products are compatible with natural rubber latex condoms and polyisoprene male condoms. These products are 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) Summary**

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**Date prepared:** 21 September 2017

**Device name:** Exsens Personal Lubricant - Pure Aqua  
Exsens Personal Lubricant - Aloe Vera  
Exsens Personal Lubricant - Fresh Mint  
Exsens Personal Lubricant - Candy Apple  
Exsens Personal Lubricant - Raspberry

**Common name:** Personal lubricant

**Classification Name:** Condom

**Classification Number:** 21 CFR § 884.5300

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

**Regulatory Class:** Class II

**Panel:** Obstetrics/Gynecology

**Predicate Device:** K-Y Marilyn Pleasure Gel, K151884

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

**Device Description:** Exsens Personal Lubricants are non-sterile, water-based personal lubricants that provide personal lubrication during intimate sexual activity. They are made up of Glycerin, Water, Propylene Glycol, Aroma (Flavor), Aloe Barbadensis (aloe vera) leaf juice, Hydroxyethylcellulose, Sodium Benzoate, Potassium Sorbate, Sodium Saccharin and citric acid. The product is packaged in a 70ml polyethylene white tube with a flip-top cap and protective sleeve. It is for over-the-counter (OTC) use.

The device specifications are listed in the table below:
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Clear gel</td>
</tr>
<tr>
<td>Odor</td>
<td>Neutral, mint, candy apple, raspberry</td>
</tr>
<tr>
<td>pH</td>
<td>5.0 – 6.0</td>
</tr>
<tr>
<td>Viscosity</td>
<td>7000 - 12,000 mPa</td>
</tr>
<tr>
<td>Density</td>
<td>1.14</td>
</tr>
<tr>
<td>Osmolality</td>
<td>600 - 700 mOsmol/kg</td>
</tr>
<tr>
<td>Antimicrobial Effectiveness</td>
<td>Meets acceptance criteria for Category 2 products</td>
</tr>
<tr>
<td>Total Microbial Count</td>
<td>&lt;100 cfu/g</td>
</tr>
<tr>
<td>Fungal/Yeast/Mold Limits</td>
<td>&lt;10 cfu/g</td>
</tr>
<tr>
<td>Absence of Pathogenic Organisms</td>
<td>Absent</td>
</tr>
</tbody>
</table>

**Indications for Use:**

Intended 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. These products are compatible with natural rubber latex condoms and polyisoprene male condoms. These products are not compatible with polyurethane condoms.

**Predicate Device Comparison:**

The table below lists the comparative intended use and technological characteristics of the subject and predicate device.

<table>
<thead>
<tr>
<th>510(K)</th>
<th>Device Name</th>
<th>Intended Use</th>
<th>Ingredients</th>
<th>Physical Features</th>
<th>Shelf life</th>
</tr>
</thead>
<tbody>
<tr>
<td>K163674</td>
<td>Exsens Personal Lubricant - Pure Aqua</td>
<td>Intended 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. These products are compatible with natural rubber latex condoms and polyisoprene male condoms. These products are not compatible with polyurethane condoms.</td>
<td>Glycerin, Water, Propylene Glycol, Aroma (Flavor) / Aloe Barbadensis (aloe vera) leaf juice, Hydroxyethylcellulose, Sodium Benzoate, Potassium Sorbate, Sodium Saccharin and citric acid.</td>
<td>Homogeneous Clear Gel, water soluble</td>
<td>1 year</td>
</tr>
<tr>
<td>K151884</td>
<td>KY Marilyn Pleasure Gel</td>
<td>Intended 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 device is</td>
<td>Water, Glycerin, Propylene Glycol, Hydroxyethylcellulose, PEG-40 Hydrogenated Castor Oil, Flavor, Benzoic Acid, and Sodium Hydroxide</td>
<td>Homogeneous Clear Gel/odorless</td>
<td>9 months</td>
</tr>
</tbody>
</table>
The subject and predicate device have the same intended use – for penile and/or vaginal application, intended to moisturize and lubricate, and to enhance the ease of comfort of intimate sexual activity and supplement the body’s lubrication. The subject and predicate device have different technological characteristics, including different formulation and shelf life. The different technological characteristics of the subject device do not raise different questions of safety and effectiveness. Also, all personal lubricants must independently demonstrate that they are biocompatible, compatible with condoms, and can maintain their specifications for their expected shelf life.

Summary of Performance Data:

Biocompatibility

Biocompatibility studies were conducted on the subject device, including cytotoxicity, sensitization, irritation, and acute systemic toxicity. Each study was conducted in accordance with GLP requirements and requirements of 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)

The results of testing demonstrated the device materials to be biocompatible.

Condom Compatibility:

The compatibility of the subject device with natural rubber latex, polyisoprene, and polyurethane male condoms was evaluated in accordance with ASTM D 7661-10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber latex Condoms. The results of this test demonstrated that the subject device is compatible with natural rubber latex and polyisoprene male condoms. This product is not compatible with polyurethane condoms.

Stability / Shelf-life:

Exsens Personal Lubricants are shown to have a 12 month shelf life according to ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. Testing on samples at 3 months of accelerated aging showed that the subject device met the device specifications as listed in this 510(k) summary.

Conclusion:

The results of the performance testing described above demonstrate that the Exsens Personal Lubricants are as safe and effective as the predicate device and supports a determination of substantial equivalence.