DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 10, 2017

You First Services, Incorporated
Jeffrey Eberhard
Quality Systems and Regulatory Affairs Manager
1576 Sweet Home Road
Amherst, New York 14228

Re: K163476
Trade/Device Name: Lubricity
Regulatory Class: Unclassified
Product Code: LFD
Dated: March 31, 2017
Received: April 3, 2017

Dear Jeffrey Eberhard:

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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163476

Device Name
Lubricity®, Artificial Saliva

Indications for Use *(Describe)*

The Lubricity® Moisturizing Mouth Spray's intended use is to relieve the symptoms of dry mouth, refresh, moisturize, soothe oral irritation and lubricate dryness in and around the oral cavity.

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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Section 5 - 510(k) Summary

Date Prepared	May 8, 2017
Submitter	You First Services, Incorporated
Primary Contact	Jeffrey Eberhard, Ph.D. Quality Systems and Regulatory Affairs Director Baird Research Complex 1576 Sweet Home Road Amherst, New York 14228 Telephone-716-204-7215 jeberhard@youfirstservices.com
Device Common Name	Saliva, artificial
Trade Name	Lubricity®
Product Code and Classification	LFD, unclassified
Predicate Device	Salinum®/Oraclair, Sinclair Pharmaceuticals, 510(k) Number K024148
Device Description	Lubricity® is an oral saliva substitute containing gel film forming polysaccharides, Sodium Hyaluronate, which has lubricating and moisturizing properties in the buccal cavity. The product is formulated, preserved and packed in blow molded polyethylene terephthalate bottles with a closure system comprising a metered dose liquid spray fitting manufactured from polypropylene, high density polyethylene, polymethoxylene copolymer and stainless steel (spring). All container closure components have appropriate status under FDA food contact or GRAS regulations. The device components are summarized in the following table. Lubricity® is equivalent to the predicate device Salinum®/Oraclair in its intended use. Both of the products are artificial saliva agents designed for relief from dry mouth symptoms.

<table>
<tr><td>Intended Use of Device</td><td>The Lubricity® Moisturizing Mouth Spray's intended use is to relieve the symptoms of dry mouth, refresh, moisturize, soothe oral irritation and lubricate dryness in and around the oral cavity.</td></tr>
<tr><td>Technological Characteristics</td><td>
<table>
<tr><td>PRODUCT NAME</td><td>Lubricity ®</td><td>Salinum®/Oraclair</td></tr>
<tr><td>INGREDIENTS</td><td>Water, Xylitol, Sodium Hyaluronate, Sodium Benzoate, Potassium Sorbate, Hydrochloric Acid</td><td>Linseed extract, Methylparaben, Propylparaben, Dipotassium phosphate</td></tr>
<tr><td>INTENDED USE</td><td>Symptomatic Treatment of Xerostomia</td><td>Symptomatic Treatment of Xerostomia</td></tr>
<tr><td>METHOD OF USE</td><td>Ready to use liquid</td><td>Ready to use liquid</td></tr>
<tr><td>APPLICATION PER DAY</td><td>3 to 4 times</td><td>As needed</td></tr>
<tr><td>DISEASE STATE</td><td>Xerostomia</td><td>Xerostomia</td></tr>
<tr><td>AREA OF USE</td><td>Oral Cavity</td><td>Oral Cavity</td></tr>
<tr><td>TYPE OF PRODUCT</td><td>Solution</td><td>Solution</td></tr>
<tr><td>PRESENTATION</td><td>Non-sterile</td><td>Non-sterile</td></tr>
</table>
</td></tr>
<tr><td>Performance Testing</td><td><u>Non-clinical Performance Testing</u>
Biocompatibility
Cytotoxicity
Delayed Hypersensitivity
Oral Mucosal Irritation
LD_{50} Short Term Toxicity
Stability Testing

<u>Clinical Performance Testing</u>
In clinical evaluation, Lubricity® met the primary study objective of improved oral lubrication with no serious adverse events.</td></tr>
<tr><td>Substantial Equivalence</td><td>The lubricating and moisturizing properties of a saliva substitute are imparted by the Sodium Hyaluronate in Lubricity®. The saliva substitute properties of the predicate are imparted by linseed extract. The subject device and the predicate protect and lubricate hard and soft surfaces of the oral cavity. The function of device components is to increase the viscosity and provide film formation.</td></tr>
</table>

	Discussion of Differences The variations in formula/composition for Lubricity® from the predicate device are as follows: The lubricating and moisturizing properties of Lubricity® are imparted by Sodium Hyaluronate and the preservatives used are Sodium Benzoate and Potassium Sorbate and Xylitol as the sweetener. The predicate device imparts its lubricating effect by the ingredient linseed extract. The preservatives used in the predicate device are Methylparaben and Propylparaben. These differences in formulation to the predicate devices do not alter the function, indications or performance of the product.
Conclusion	Based upon similarities in intended use, and on the results of non-clinical and clinical performance testing, Lubricity® is found to be substantially equivalent to the predicate device Salinum®/Oraclair identified in K024148.