May 19, 2025

Rowpar Pharmaceuticals Inc.
℅ Steven Weisman
Global President
Innovative Science Solutions (D.B.A Lumanity)
10 N Park Place
Suite 201
Morristown, New Jersey 07960

Re: K250390
Trade/Device Name: CloSYS® Dry Mouth Sensitive Mouth Rinse
Regulatory Class: Unclassified
Product Code: LFD
Dated: February 3, 2025
Received: April 11, 2025

Dear Steven Weisman:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250390

Device Name

ClōSYS® Dry Mouth Sensitive Mouth Rinse

Indications for Use *(Describe)*

Relieves the symptom and discomfort of dry mouth, refreshes, moisturizes/hydrates, and lubricates oral dryness.

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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SECTION 5: 510(K) Summary K250390

1. APPLICANT INFORMATION

Name: Rowpar Pharmaceuticals, Inc.
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Bridgewater, NJ 08807
Contact Person: Michael Tune
Telephone: +1 (901) -384-9070
Email ID: mtune@arcadiach.com
Date Summary Prepared: 06 May 2025

2. SUBMITTER INFORMATION

Name: Innovative Science Solutions (D.B.A Lumanity)
Address: 10 N Park Place
Suite 201, Morristown NJ 07960
Contact Person: Steven M. Weisman
Telephone: +1 (973) -816-1130
Email ID: Steven.Weisman@lumanity.com

3. DEVICE NAME

Device Name: ClōSYS® Dry Mouth Sensitive Mouth Rinse
Trade or Proprietary Name: ClōSYS® Dry Mouth Sensitive Mouth Rinse
Common or Usual Name: Saliva, Artificial
Classification Name (if known): Saliva, Artificial

4. IDENTIFICATION OF EQUIVALENCE

GlaxoSmithKline Consumer Healthcare: Biotène Dry Mouth Mouthwash & Biotène PBF Dry Mouth Mouthwash cleared in K123731 – Predicate Device.
Biopharm Consults LLC: Hydris™ Oral Rinse cleared in K163029 – Reference Device

5. DEVICE DESCRIPTION

ClōSYS® Dry Mouth Sensitive Mouth Rinse is an oral rinse designed to alleviate the symptoms of dry mouth for home use. The formulation includes water, humectants/ moisturizers, flavors,

sweeteners, as well as ingredients with lubricating, soothing, and refreshing properties. The product is a ready-to-use, non-sterile, semi-viscous clear liquid, packaged in 16.0 FL OZ white High-Density Polyethylene (HDPE) bottles within a carton. Accelerated stability testing of the finished product supports a shelf life of 2 years. The rinse is formulated to have similar properties as predicate product Biotene Dry Mouth Oral Rinse Fresh Mint, which is a medical device 510(k) Number K123731 and the reference device Hydris™ Oral Rinse cleared under K163029. ClōSYS® Dry Mouth Sensitive Mouth Rinse will be available in 16 fl oz (473 mL) PET bottles in a carton.

6. STATEMENT OF INDICATIONS FOR USE

Relieves the symptom and discomfort of dry mouth, refreshes, moisturizes/hydrates, and lubricates oral dryness.

7. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS

Attribute	ClōSYS® Dry Mouth Sensitive Mouth Rinse (Subject Device)	Biotène Dry Mouth Mouthwash & Biotène PBF Dry Mouth Mouthwash K123731 (Predicate)	Hydris™ Oral Rinse K163029 (Reference)
Product Code/Panel	LFD/Dental	LFD/Dental	LFD/Dental
Indications for Use	Relieves the symptom and discomfort of dry mouth, refreshes, moisturizes/hydrates, and lubricates oral dryness.	Relieves the symptoms of dry mouth; refreshes, moisturizes, cleans, soothes oral irritation, and lubricates oral dryness	Relieves the symptoms and discomfort of dry mouth, refresh, moisturize/hydrate, clean, soothe oral irritation and lubricate oral dryness.
Method of Use	Ready to use liquid	Ready to use liquid	Ready to use liquid
Applications Per Day	Up to 5 times a day	Up to 5 times a day	Up to 2 times a day
Dosage (Per Use)	15 mL	15 mL	20 mL
Disease State	Xerostomia	Xerostomia	Xerostomia
Presentation	Non-Sterile	Non-Sterile	Non-Sterile
Environment of Use	Household	Household	Household
Solvent	Water	Water	Water
Moisturizers	Glycerin	Glycerin, Propylene Glycol	Glycerin, Propylene Glycol
Sweetener/Humectants	Xylitol, Sorbitol	Xylitol, Sorbitol	Xylitol, Sorbitol
Thickeners	Hydroxyethyl Cellulose	Hydroxyethyl Cellulose	Cellulose Gum, Xanthan Gum, Carbomer
pH Buffers	Citric Acid	Disodium Phosphate, Sodium Phosphate	Disodium Phosphate, Sodium Phosphate

8. DISCUSSION OF DIFFERENCES

There are certain differences between the proposed device and its predicate devices, specifically in the formulation of ClōSYS® Dry Mouth Sensitive Mouth Rinse. The variations in ingredients are primarily to ensure compatibility with the formula and flavor and for achieving desired stability. However, these modifications do not impact the safety profile of the product. The other variations in the formula/composition involve differences in the concentration and volume of common ingredients to ensure proper dispensing and use of the product. These changes do not affect the function, indications, or equivalency of the proposed product. In summary, the differences in formulation compared to the predicate devices do not alter the function, indications, efficacy, or substantial equivalency of the products.

9. DISCUSSION AND CONCLUSIONS FROM THE NONCLINICAL AND CLINICAL TESTS

ClōSYS® Dry Mouth Sensitive Mouth Rinse has been shown in non-clinical studies to be safe (Biocompatibility Assessments) and stable (Stability Studies) for its intended use. The standard biocompatibility testing such as Sensitization, Mucosal Irritation and Cytotoxicity was conducted using the subject device's finished final form. The testing was conducted in accordance with ISO 10993 Biological Evaluation of Medical Devices, as recognized by the FDA. The assays demonstrated an acceptable biocompatibility profile consistent with the predicate. Stability of the finished product is monitored at room temperature and under accelerated conditions.

No other clinical tests were performed.

ClōSYS® Dry Mouth Sensitive Mouth Rinse has the same intended use and the same technology as that of the legally marketed predicate device, Biotene® Dry Mouth Oral Rinse® and reference device Hydris™ Oral Rinse . This is demonstrated by comparing the proposed device and predicate devices indications for use, technological characteristics and performance data. Results from the biocompatibility assessment and performance testing further demonstrate substantial equivalence.

This 5l0(k) summary is submitted in accordance with the requirements of 21 CFR 807.