February 12, 2021

PCCA, Inc.
Gus Bassani
Chief Scientific Officer
9901 S. Wilcrest Drive
Houston, Texas 77099

Re: K203091
Trade/Device Name: MucoLock Oral Gel
Regulatory Class: Unclassified
Product Code: OLR
Dated: October 12, 2020
Received: October 13, 2020

Dear Gus Bassani:

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,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203091

Device Name
MucoLock Oral Gel

Indications for Use *(Describe)*
MucoLock has a mechanical action which provides management of pain and relief of pain by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: Oral Mucositis or Stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery, traumatic ulcers caused by braces and ill-fitting dentures, or disease. Also indicated for diffuse aphthous ulcers.

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 K203091

Owner's Name: PCCA
Address: 9901 South Wilcrest Dr.
Houston, TX 77099-5132
Phone Number: (832) 295-1218

Contact Person: Gus Bassani, Pharm.D.
PCCA

Date of Preparation: February 7, 2021

Device Name: MucoLock® Oral Gel
Common Name: MucoLock® Oral Gel
Classification: Oral Wound Dressing
Regulatory class: I, Unclassified
Product Code: OLR

Legally Marketed Device:
K081372 - GELX Oral Gel

Device Description:
MucoLock® is a low viscosity, pourable, and swish-able gel, which is presented in 16 fl. oz. bottles. This product, when washed around the mouth, forms a protective layer over the oral mucosa.

Indications for Use:
MucoLock has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: Oral Mucositis or Stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery, traumatic ulcers caused by braces or ill-fitting dentures, or disease. Also indicated for diffuse aphthous ulcers.

Summary of Technological Characteristics of the Device Compared to the Predicate Device:
With the exception of the product name, MucoLock has the same intended/indications for use as the predicate GelX Oral Gel.

Product Name	**Subject Device:** **PCCA MucoLock (K203091)**	**Predicate Device:** **GelX Oral Gel (K081372)**
Ingredients	Water, Isomalt, Pullulan, Glycerin, Beta-glucan, Sodium Hyaluronate, Tamarindus Indica Seed Polysaccharide, Zea Mays (Corn) Starch, Poloxamer 407, Carbomer, Disodium EDTA, Sodium Benzoate, Potassium Sorbate, Methylparaben, Propylparaben.	Purified Water, PVP, Taurine, Zinc Gluconate, PEG-40 Hydrogenated Castor Oil, Sodium Saccharin, Sodium Hydroxide, Flavor.
Method of Use	Use undiluted	Use undiluted
Number of applications per day	Rinse around the mouth, or the affected area of the mouth for at least one minute or as long as possible to coat all oral tissue thoroughly. Spit out. Use 3 times a day or as needed as directed by your doctor. **MucoLock**® Oral Gel is to be used no longer than the timeframe prescribed by the doctor or dentist, ideally no longer than the period of time wherein oral ulcers, lesions, irritation, mucositis or stomatitis persists.	Rinse around the mouth for at least one minute or as long as possible to coat tongue, palate, throat, inside of cheeks and all oral tissue thoroughly. Use 3 times a day or as needed. Do not eat or drink for least one hour following treatment.
Claim	Management of pain and relief of pain.	Management of pain and relief of pain.
Area of Use	Oral Mucosa	Oral Mucosa
Disease State	Oral Mucositis/ Stomatitis/Oral Lesions	Oral Mucositis/ Stomatitis/Oral Lesions
Type of Product	Ready for use	Ready for use
Presentation	Non-Sterile	Non-Sterile

Comparison to Predicate Device:

The mode of action of MucoLock Oral Gel, which is via the formation of a protective layer over the oral mucosa, is similar to GelX.

While the chemical composition of film-forming polymers, preservatives and sweeteners differ, the differences do not raise concerns of safety and effectiveness because all MucoLock ingredients are listed in the GRAS SCOGS Database, in the GRAS Notice Inventory, or are commonly utilized in other approved oral products at levels consistent with those uses in the Inactive Ingredient Database. In addition, the proposed MucoLock Oral Gel features similar indications for use language, technological characteristics, and mode of action as stated above.

Non-Clinical Testing Summary:

Standard	Biocompatibility Testing	Result Summary
ISO 10993-5: 2009	Cytotoxicity	Not Cytotoxic
ISO 10993-10: 2010	Buehler Guinea Pig Skin Sensitization Test	Not Sensitizing
ISO 10993-10: 2010	Primary Direct Oral (Buccal) Irritation Test	Non-Irritant to the buccal tissues

Performance Testing	Result Summary
Bioadhesiveness	The adherence and retention time of the fluorescently labelled gel on the human oral buccal tissue constructs were similar for both the subject and device in the predicate family.

Clinical Performance Testing:

Clinical performance testing is not included.

Conclusion:

Based upon similarities in indications for use and technology, together with the results of non - clinical performance testing, we believe that MucoLock is substantially equivalent to the predicate device GelX.