March 11, 2024

EUSA Pharma (UK) Limited
% Angela Blackwell
Senior Consultant
Blackwell Device Consulting
3207 SE 156th Ave
Portland, Oregon 97236

Re: K234015
Trade/Device Name: Caphosol® Artifical Saliva (32 doses sachet box)
Regulatory Class: Unclassified
Product Code: LFD
Dated: December 14, 2023
Received: December 19, 2023

Dear Angela Blackwell:

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.

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
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234015

Device Name

Caphosol® Artifical Saliva (32 doses sachet box)

Indications for Use *(Describe)*

Caphosol® is indicated for dryness of the mouth or throat (hyposalivation, xerostomia), regardless of the cause and regardless of whether the conditions are temporary or permanent. Caphosol® is also indicated as an adjunct to standard oral care in treating mucositis that may be caused by radiation or high dose chemotherapy. Relief of dryness of the oral mucosa in these conditions is associated with an amelioration of pain.

Caphosol® may be used for relief of dryness of the oral mucosa when hyposalivation results from the following: surgery, radiotherapy near the salivary glands, chemotherapy, infection or dysfunction of the salivary glands; inflammation of the mouth or throat; fever; emotional factors such as fear or anxiety; obstruction of the salivary ducts; Sjogren's syndrome; and Bell's Palsy.

Caphosol® is also indicated for dryness of the oral mucosa due to drugs such as antihistamines or atropine or other anticholinergic agents that suppress salivary secretion.

It may be used as part of an oral hygiene program for patients with dry mouth. Caphosol® provides intensive hygiene of the oral cavity, and may be used to help relieve bad taste and to relieve offensive nasal discharge and crusting.

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.

Caphosol® Artificial Saliva
510(k) Summary K234015
December 4, 2023

Name and Address: EUSA Pharma (UK) Ltd
Breakspear Park, Breakspear Way
Hemel Hempstead HP2 4TZ United Kingdom

Contact Person: Dr. Sandy Suh
Email: suh.s@recordati.com
Telephone: (908) 849-4908

Name of device: Caphosol® Artificial Saliva
Product Code Name: artificial saliva
Primary Product Code: LFD
Regulatory Class: unclassified

Submission Contact:

Angela Blackwell
Blackwell Device Consulting
P.O. Box 718
Gresham, OR 97030-0172
(704)450-9934
angela@blackwelldevice.com

Device Description: Caphosol® is an electrolyte solution resembling human saliva, designed in part to replace the normal ionic and pH balance in the oral cavity. It is intended as a mouth rinse to moisten, lubricate, and clean the oral cavity including the mucosa of the mouth, tongue, and throat. Caphosol® maintains moistness in the oral cavity. It relieves diffuse dryness and fissuring of the: oral mucosa, as well as painful tongue conditions due to hyposalivation. Patients having this condition are also prone to dental caries and candidal infections.

Caphosol® is a partial substitute for natural saliva. Caphosol® facilitates chewing and speaking; loosens tough mucus; prevent mucous membranes from sticking together, helps remove nasal crust and relieve nasal soreness; improves adherence of dentures, and also relieves bad taste. Caphosol® is an adjunct to standard oral care for treating mucositis that may be caused by radiation or high dose chemotherapy. Relief of dryness of the oral mucosa in these conditions is associated with an amelioration ·of pain.

Caphosol® is a preparation comprising two separately packaged aqueous solutions, a phosphate solution (Caphosol® A) and a calcium solution (Caphosol® B) which when both sachet solutions are combined in equal volumes form a solution supersaturated with respect to both calcium and phosphate ions. The solution after mixing the contents of solutions A and B contains:

Ingredients:	% w/w
Dibasic Sodium Phosphate	0.032
Monobasic Sodium Phosphate	0.009
Calcium Chloride	0.052
Sodium Chloride	0.569
Purified Water	99.338

Indications for Use: Caphosol® is indicated for dryness of the mouth or throat (hyposalivation, xerostomia), regardless of the cause and regardless of whether the conditions are temporary or permanent. Caphosol® is also indicated as an adjunct to standard oral care in treating mucositis that may be caused by radiation or high dose chemotherapy. Relief of dryness of the oral mucosa in these conditions is associated with an amelioration of pain.

Caphosol® may be used for relief of dryness of the oral mucosa when hyposalivation results from the following: surgery, radiotherapy near the salivary glands, chemotherapy, infection or dysfunction of the salivary glands; inflammation of the mouth or throat; fever; emotional factors such as fear or anxiety; obstruction of the salivary ducts; Sjogren's syndrome; and Bell's Palsy.

Caphosol® is also indicated for dryness of the oral mucosa due to drugs such as antihistamines or atropine or other anticholinergic agents that suppress salivary secretion.
It may be used as part of an oral hygiene program for patients with dry mouth. Caphosol® provides intensive hygiene of the oral cavity, and may be used to help relieve bad taste and to relieve offensive nasal discharge and crusting.

Testing Summary: No performance testing was conducted.

Shelf Life: Accelerated shelf life testing equivalent to 3 years was conducted both on the package to make sure its integrity was intact at the end of 3 years equivalent and on the liquids to make sure the solutions did not exhibit microbial growth over the 3 years equivalent. This same type of testing was conducted on the predicate device with the only difference being in the shelf life package testing protocol needing to change slightly to be for a flexible package rather than a rigid one.

Predicate Device: Caphosol® (in vials) K030802

Substantial Equivalence:

Caphosol® has not changed its composition or indications for use. The only difference between the subject device and the predicate device is the package, the subject device is in sachets and the predicate device is in vials.

	Caphosol® Artificial Saliva in sachets Subject Device	Caphosol® Artificial Saliva in vials Predicate Device K030802
Product Code	LFD	LFD
Indications for Use	Caphosol® is indicated for dryness of the mouth or throat (hyposalivation, xerostomia), regardless	Caphosol® is indicated for dryness of the mouth or throat (hyposalivation, xerostomia), regardless

	of the cause and regardless of whether the conditions are temporary or permanent. Caphosol® is also indicated as an adjunct to standard oral care in treating the mucositis that may be caused by radiation or high dose chemotherapy. Relief of dryness of the oral mucosa in these conditions is associated with an amelioration of pain. Caphosol® may be used for relief of dryness of the oral mucosa when hyposalivation results from the following: surgery, radiotherapy near the salivary glands, chemotherapy, infection or dysfunction of the salivary glands; inflammation of the mouth or throat; fever; emotional factors such as fear or anxiety; obstruction of the salivary ducts; Sjogren's syndrome; and Bell's Palsy. Caphosol® is also indicated for dryness of the oral mucosa due to drugs such as antihistamines or atropine or other anticholinergic agents that suppress salivary secretion. It may be used as part of an oral hygiene program for patients with dry mouth. Caphosol® provides intensive hygiene of the oral cavity, and may be used to help relieve bad taste and to relieve offensive nasal discharge and crusting.	of the cause and regardless of whether the conditions are temporary or permanent. Caphosol® is also indicated as an adjunct to standard oral care in treating the mucositis that may be caused by radiation or high dose chemotherapy. Relief of dryness of the oral mucosa in these conditions is associated with an amelioration of pain. Caphosol® may be used for relief of dryness of the oral mucosa when hyposalivation results from the following: surgery, radiotherapy near the salivary glands, chemotherapy, infection or dysfunction of the salivary glands; inflammation of the mouth or throat; fever; emotional factors such as fear or anxiety; obstruction of the salivary ducts; Sjogren's syndrome; and Bell's Palsy. Caphosol® is also indicated for dryness of the oral mucosa due to drugs such as antihistamines or atropine or other anticholinergic agents that suppress salivary secretion. It may be used as part of an oral hygiene program for patients with dry mouth. Caphosol® provides intensive hygiene of the oral cavity, and may be used to help relieve bad taste and to relieve offensive nasal discharge and crusting.
Device Description	Caphosol® is an electrolyte solution resembling human saliva, designed in part to replace the normal ionic and pH balance in the oral cavity. It is intended as a mouth rinse to moisten, lubricate, and clean the oral cavity including the mucosa of the mouth, tongue and throat. Caphosol® maintains moistness in the oral cavity.	Caphosol® is an electrolyte solution resembling human saliva, designed in part to replace the normal ionic and pH balance in the oral cavity. It is intended as a mouth rinse to moisten, lubricate, and clean the oral cavity including the mucosa of the mouth, tongue and throat. Caphosol® maintains moistness in the oral cavity.

	It relieves diffuse dryness and fissuring of the oral mucosa, as well as painful tongue conditions due to hyposalivation. Patients having this condition are also prone to dental caries and candidal infections. Caphosol® is a partial substitute for natural saliva. Caphosol® facilitates chewing and speaking; loosens tough mucus; prevent mucous membranes from sticking together, helps remove nasal crust and relieve nasal soreness; improves adherence of dentures, and also relieves bad taste. Caphosol® is an adjunct to standard oral care for treating the mucositis that may be caused by radiation or high dose chemotherapy. Relief of dryness of the oral mucosa in these conditions is associated with an amelioration ·of pain. Caphosol® is a preparation comprising two separately packaged aqueous solutions, a phosphate solution (Caphosol® A) and a calcium solution (Caphosol® B) which when both sachet solutions are combined in equal volumes form a solution supersaturated with respect to both calcium and phosphate ions.	It relieves diffuse dryness and fissuring of the oral mucosa, as well as painful tongue conditions due to hyposalivation. Patients having this condition are also prone to dental caries and candidal infections. Caphosol® is a partial substitute for natural saliva. Caphosol® facilitates chewing and speaking; loosens tough mucus; prevent mucous membranes from sticking together, helps remove nasal crust and relieve nasal soreness; improves adherence of dentures, and also relieves bad taste. The purpose of this premarket notification is to expand the claims for Caphosol® to allow Caphosol® to be marketed as an adjunct to standard oral care for treating the mucositis that may be caused by radiation or high dose chemotherapy. Relief of dryness of the oral mucosa in these conditions is associated with an amelioration ·of pain. Caphosol® is a preparation comprising two separately packaged aqueous solutions, a phosphate solution (Caphosol® A) and a calcium solution (Caphosol® B) which when both ampoule solutions when combined in equal volumes form a solution supersaturated with respect to both calcium and phosphate ions.
Composition % w/w	Dibasic Sodium Phosphate 0.032 Monobasic Sodium Phosphate 0.009 Calcium Chloride 0.052 Sodium Chloride 0.569 Purified Water 99.338	Dibasic Sodium Phosphate 0.032 Monobasic Sodium Phosphate 0.009 Calcium Chloride 0.052 Sodium Chloride 0.569 Purified Water 99.338
Package	sachets	vials
Shelf Life	3 years	3 years
Shelf Life testing includes liquid and package testing	Yes	Yes

Conclusion: Caphosol® in sachets is substantially equivalent to the predicate device Caphosol® in vials K030802. They have the same indications, similar device description, similar testing, and the same composition. Shelf life testing is similar to the shelf life testing of the predicate device with only minor differences due to the change in packaging. Both packages are tested for shelf life using scientifically valid methods so any differences in methods changing from a rigid to a soft container do not change the substantial equivalence of the devices.