DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Eusa Pharma (UK) Limited
% Mr. J. Harvey Knauss
Consultant
Delphi Consulting Group
11874 South Evelyn Circle
Houston, Texas 77071-3404

March 31, 2017

Re: K162167
Trade/Device Name: Caphosol Artificial Saliva Tablets
Regulatory Class: Unclassified
Product Code: LFD
Dated: March 7, 2017
Received: March 7, 2017

Dear Mr. Knauss:

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,

Susan Runner DDS, MA

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)*
K162167

Device Name
CAPHOSOL Artificial Saliva

Indications for Use *(Describe)*

Caphosol Dispersible is indicated for dryness of the mouth and throat (hyposalivation, xerostomia), regardless of the cause and regardless of whether the condition is temporary or permanent. Caphosol Dispersible is also indicated as an adjunct to standard oral care in the treatment of 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 amelioration of pain.

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, K162167, GENERAL INFORMATION:

Sponsor/Submitter:	**EUSA Pharma** Breakspear Park, Breakspear Way Hemel Hempstead HP2 4TZ United-Kingdom 011 44 1732 832 317 voice Registration # 10049906 Mr. Paul Davisson

Common/Usual Name :	**None**
Proprietary Name:	**Caphosol Artificial Saliva**
Regulation Number:	**Unclassified**
Product Code:	**LFD**
Predicate Devices:	**K030802 Primary**

Description of the device and its intended application:

Caphosol is a supersaturated calcium phosphate, electrolyte mouth rinse used as artificial saliva, designed in part to replace ionic and pH balance in the oral cavity, and formulated as a tablet to be dissolved in water prior to use.

The following table lists the Caphosol components:

List of components	Function in Caphosol Dispersible	Function in Caphosol
Sodium phosphate dibasic anhydrous	Active component	Active component
Sodium phosphate monobasic anhydrous	Active component	Active component
Calcium chloride	Active component	Active component
Sodium hydrogen carbonate	Effervescent Agent	Stabilizer
Sodium carbonate anhydrous	Effervescent Agent	none
Maltodextrin	Diluent	none
Granulate Citric acid anhydrous/sorbitol	Effervescent Agent	none
Water		Active component

Caphosol Statement of Intended Use*:*

Caphosol Dispersible is indicated for dryness of the mouth and throat (hyposalivation, xerostomia), regardless of the cause and regardless of whether the condition is temporary or permanent. Caphosol Dispersible is also indicated as an adjunct to standard oral care in the treatment of 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 amelioration of pain.

Comparison of Device Technology:

COMPARING	CAPHOSOL® Dispersible K162167	CAPHOSOL® Predicate K030802
Product Code	LFD	LFD
Regulation Number	Unclassified	Unclassified
Indication for Use	Caphosol Dispersible is indicated for dryness of the mouth and throat (hyposalivation, xerostomia), regardless of the cause and regardless of whether the condition is temporary or permanent. Caphosol Dispersible is also indicated as an adjunct to standard oral care in the treatment of 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 amelioration of pain.	Caphosol is indicated for dryness of the mouth or throat (hypo salivation, xerostomia), regardless of the cause and regardless of whether the condition is temporary or permanent. Caphosol is indicated for relief of dryness of the oral mucosa when hypo salivation 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.

COMPARING	CAPHOSOL® Dispersible K162167	CAPHOSOL® Predicate K030802
		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.
Packaging	Tablet solid form, 1.75 MM diameter. 	• Two 15 ml solutions plastid (LDPE) ampules • Solution A (blue ampule) – (phosphate solution) Solution B (clear ampule) – (calcium solution) 
Method of use	Ready to use, mix with water.	Mix solutions A & B
Area of use	Oral cavity.	Oral cavity.
Presentation	Non-Sterile.	Non-Sterile.
Interaction with other medicinal products	There are no known interactions with medicinal or other products.	There are no known interactions with medicinal or other products.

Indication for Use Differences:
The indication for use statement of the predicate device is more specific than the indication for use statement of the subject device. The differences do not raise concerns as the intended use is the same.

Technology Differences:

The CAPHOSOL® Artificial Saliva Tablets and Caphosol® Liquid Artificial Saliva active chemical components are identical, however the CAPHOSOL® Artificial Saliva Tablets formulation includes a diluent and effervescent agents, and does not contain water. The available physical form of the subject device is a dry tablet, whereas the predicate device is composed of two ampules containing different solutions to be mixed prior to use. The

excipients in the subject device formulation result in effervescence and complete dissolution of the table to obtain the final solution. The solution prepared after dissolution of a tablet or after mixing 2 ampules are identical in quantity of the active ingredients (Calcium and Phosphate).

The CAPHOSOL® Artificial Saliva Tablets is substantially equivalent to the predicate devices with regard to operating principle and function.

Performance Testing:

Biocompatibility assessment conducted in accordance with ISO - 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process.

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Non-Clinical and Clinical Studies:

Clinical performance testing was not conducted for the subject device.

A literature search has not shown any clinically significant adverse effects being reported.

Conclusion:

Based on the similarities in intended use, technology, and performance testing, the CAPHOSOL Artificial Saliva Effervescent Tablets is substantially equivalent to the predicate device.