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

December 23, 2015

Forward Science LLC
Mr. Brian Pikkula
President
3944 Bluebonnet Dr.
Stafford, Texas 77477

Re: K152406
Trade/Device Name: SalivaMAX™
Regulation Number: N/A
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: LFD
Dated: November 12, 2015
Received: November 13, 2015

Dear Mr. Pikkula:

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 yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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4. Indications for Use

Applicant: **Forward Science LLC**
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Stafford, TX 77477
Ph: 855-696-725
Fax: 855-329-6725

510(k) Number: K152406

Device Name: **SalivaMAX™**

Indications For Use:

SalivaMAX™ is indicated for dryness of the mouth or throat (hyposalivation, xerostomia, mucositis), regardless of the cause and regardless of whether the condition is temporary or permanent. Relief of dryness of the oral mucosa in these conditions is associated with an amelioration of pain.

SalivaMAX™ is also indicated as an adjunct to standard oral care in treating the mucositis that may be caused by radiation or high dose chemotherapy.

SalivaMAX™ may be used for the relief of dryness of the oral mucosa when hyposalivation results from the following: pre/post surgery, radiotherapy, 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, Bell's Palsy, and Sjogren's syndrome. SalivaMAX™ is also indicated for dryness of the oral mucosa due to drugs such as antihistamines, atropine, or other anticholinergeic agents that suppress salivary secretion.

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

Prescription Use____X____ AND/OR Over-the-Counter_____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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5. 510(k) SUMMARY

Submitted by: Forward Science LLC
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Ph: 855-696-7254
Fax: 855-329-6725

Contact Person: Brian Pikkula, PhD

Date Prepared: December 16, 2015

Proprietary Name: SalivaMAX™

Common Name: Artificial Salvia

Classification Name: Unclassified

Device Class: Unclassified (Pre-Amendment)

Panel: Dental

Product Code: LFD

Predicate Devices: *Primary Predicate*
Neutrasal (K093642)
Invado Pharmaceuticals
25 Ravenna Drive
Pomona, NY, 10970

Reference Predicate
Caphosol (K030802)
Inpharma A.S.
New England Biomedical Research, Incorporated
96 West Main Street.
P.O. Box 809
Northborough, MA 01532

Device Description:

SalivaMAX™ is an artificial saliva that is provided in disposable packets.

SalivaMAX™ is comprised of powdered ingredients that when combined with 30 mL (1 oz.) of water, produces a supersaturated calcium phosphate solution. SalivaMAX™ is packaged in single-use packets and will be provided non-sterile and is not intended to be sterilized before use.

Because SalivaMAX™ is to be administered several times per day it will primarily be used at home, office or other non-clinical settings. However, SalivaMAX™ may also be used in clinical or healthcare facility settings where patients are receiving inpatient services.

The goal of administering SalivaMAX™ is to relieve chronic and temporary xerostomia and mucositis. SalivaMAX™ is a partial substitute for natural saliva and intended to moisten, lubricate,

and clean the oral cavity including the mucosa of the mouth, tongue, and throat. SalivaMAX™ facilitates chewing and speaking; and can relieve bad breath.

SalivaMAX™ is composed of US Pharmacopeia grade calcium, phosphate, bicarbonate, and chloride electrolytes. Each application of SalivaMAX™ is to swish half the solution for 1 minute, expectorate, then repeat for the remaining solution. Given that the rinse is topical with a maximum rinse time of 20 minutes per day (2 minutes per application x maximum 10 times per day), SalivaMAX™ is considered a surface contacting device with a limited duration of contact.

Key performance specifications of SalivaMAX™ are an in solution pH range of 6.25 - 7.5 and solubility in water.

Intended Use:

SalivaMAX™ is indicated for dryness of the mouth or throat (hyposalivation, xerostomia, mucositis), regardless of the cause and regardless of whether the condition is temporary or permanent. Relief of dryness of the oral mucosa in these conditions is associated with an amelioration of pain.

SalivaMAX™ is also indicated as an adjunct to standard oral care in treating the mucositis that may be caused by radiation or high dose chemotherapy.

SalivaMAX™ may be used for the relief of dryness of the oral mucosa when hyposalivation results from the following: pre/post surgery, radiotherapy, 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, Bell's Palsy, and Sjogren's syndrome. SalivaMAX™ is also indicated for dryness of the oral mucosa due to drugs such as antihistamines, atropine, or other anticholinergeic agents that suppress salivary secretion.

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

Substantial Equivalence

Between the subject device to the primary predicate, NeutraSal (K093642), there are no technological differences.

Comparing the subject device to the reference predicate, Caphosol (K030802), there are two technological differences. First, Caphosol is provided in a two vial, liquid package. This difference does not change its substantial equivalence because both the subject device and the reference predicate are a supersaturated calcium phosphate rinse when applied. The other technological difference from the reference predicate is the addition of sodium bicarbonate and silicon dioxide in the subject device.

Note, however, that sodium bicarbonate and silicon dioxide are ingredients in the primary predicate, NeutraSal. Therefore, the subject device is substantially equivalent to the primary predicate Neutrasal as the ingredients in the subject device and the primary predicate are the same.

SalivaMAX™ and the predicates, Neutrasal (primary predicate K093642) and Caphosol (reference predicate K030802) share the same labeling and intended uses, operation principles, and technical characteristics. Each uses supersaturated calcium phosphate as a partial substitute for natural saliva to relieve dry mouth. Therefore, SalivaMAX™ and the predicates, Neutrasal and Caphosol are substantially equivalent.

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Table 1. Comparison of Subject Device and Predicates

Comparison Parameters	*Subject Device*	*Primary Predicate*	*Reference Predicate*
	SALIVAMAX™	**NeutraSal** (K093642)	**Caphosol** (K030802)
Intended Use	SalivaMAX™ is indicated for dryness of the mouth or throat (hyposalivation, xerostomia, mucositis), regardless of the cause and regardless of whether the condition is temporary or permanent. Relief of dryness of the oral mucosa in these conditions is associated with an amelioration of pain. SalivaMAX™ is also indicated as an adjunct to standard oral care in treating the mucositis that may be caused by radiation or high dose chemotherapy. SalivaMAX™ may be used for the relief of dryness of the oral mucosa when hyposalivation results from the following: pre/post surgery, radiotherapy, 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, Bell's Palsy, and Sjogren's syndrome. SalivaMAX™ is also indicated for dryness of the oral mucosa due to drugs such as antihistamines, atropine, or other anticholinergeic agents that suppress salivary secretion. SalivaMAX™ may be used as part of an oral hygiene program for patients with dry mouth. SalivaMAX™ provides intensive hygiene of the oral cavity, and may be used to help relieve bad taste, relieve offensive nasal discharge, and crusting.	(OTC) Neutrasal is indicated for the dryness of the mouth (hyposalivation, xerostomia). (OTC) Neutrasal 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. (OTC): Neutrasal may be used as part of an oral hygiene program for patients with dry mouth. Neutrasal also provides intensive hygiene of the oral cavity. (Rx): Neutrasal is also indicated as an adjunct to standard oral care in relieving the discomfort associated with oral 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. (Rx): Neutrasal 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; fever; emotional factors such as fear or anxiety; obstruction of the salivary ducts; Sjogren's syndrome.	Caphosol is indicated for dryness of the mouth or throat (hyposalivation, xerostomia), regardless of the cause and regardless of whether the conditions is 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 tlie oral cavity, and may be used to help relieve bad taste and to relieve offensive nasal discharge and crusting.

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Comparison Parameters (cont.)	*Subject Device*	*Primary Predicate*	*Reference Predicate*
	SALIVAMAX™	**NeutraSal** (K093642)	**Caphosol** (K030802)
Area of Use	Oral cavity	Oral cavity	Oral cavity
Formulation in Solution	Supersaturated Calcium Phosphate	Supersaturated Calcium Phosphate	Supersaturated Calcium Phosphate
Disease State	Xerostomia and mucositis	Xerostomia and mucositis	Xerostomia and mucositis
Applications /Day	2 - 10 as directed by physician and severity	2 - 10 as directed by physician and severity	2 - 10 as directed by physician and severity
pH	6.69 (in solution)	6.72 (in solution)	unknown
Solubility	Soluble in water	Soluble in water	Soluble in water (already in solution)
Prescription/ OTC	Prescription	Prescription/OTC	Prescription
Packaging	Powder in sealed packet	Powder in sealed packet	Liquid in 2 sealed vials
Shelf life	2 years	2 years	unknown
Environment of Use	Home and Clinic	Home and Clinic	Home and Clinic
Sterility	Non-sterile	Non-sterile	Non-sterile

Summary of Testing

Bench testing comparing SalivaMAX™ and Neutrasal were performed. The results were equivalent for SalivaMAX™ and the primary predicate, Neutrasal, providing further evidence of substantial equivalence. The testing consisted of:

- Dissolution Tests
- pH evaluation

Conclusion

SalivaMAX™ is substantially equivalent to the primary predicate, NeutraSal, and the reference predicate, Caphosol, in that they share a principal technological characteristic; a supersaturated calcium phosphate rinse. They also possess a similar intended use of which the primary indication is the treatment of xerostomia and mucositis.

Additionally, the subject device, SalivaMAX™, obtained similar results in bench testing (dissolution and pH evaluation) as the primary predicate, NeutraSal, giving further credence to its substantial equivalence.