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 30, 2015

MedActive Oral Pharmaceuticals, LLC
Mr. Brian Walker
Purchasing and Quality Manager
6293 West Linebaugh Avenue
Tampa, FL 33625

Re: K152201
Trade/Device Name: MedActive Oral Gel, MedActive Oral Spray
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: LFD
Dated: December 1, 2015
Received: December 2, 2015

Dear Mr. Walker:

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

K152201/S002

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K152201

Device Name: MedActive Oral Gel and MedActive Oral Spray

Indications for Use:

1. Provides symptom relief from Dry Mouth and low saliva including:

- Oral discomfort
- Mucosal soft tissue dryness
- Oral side effects of illness, therapies, and medications

2. Soothes moistens and lubricates
3. Hydrates soft tissue

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X_____ (21 CFR 801 Subpart C)

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

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5. 510(k) Summary

Submitter:

Company:	MedActive Oral Pharmaceuticals, LLC.
Street:	6293 W Linebaugh Ave
City, State Zip:	Tampa, Fl. 33625
Country:	USA
Estab. Registration #:	Unknown
Correspondent:	Brian Walker
	Purchasing and Quality Manager
Phone:	813-792-5335 x 108
Fax:	813-792-5445
Email:	brianw@medactive.com
Date:	December 29, 2015

Name of Device

Proprietary Name:	MedActive Oral Gel, MedActive Oral Spray
Classification Name:	Saliva, Artificial
	Unclassified, pre-amendment
Common Name:	Saliva, Artificial
Product Code:	LFD

Predicate Devices

Primary Device	**510(k)**
Biotene Moisturizing Mouth Spray	K123731
Reference Devices	**510(k)**
GC Moisturizing Gel	K101346
Laclede Oral Balance Liquid/ Gel	K061331

Description

MedActive Oral Gel and Spray are liquid delivery systems for ingredients that coat the inside of the mouth for a period of time and create relief from dry mouth symptoms in those who suffer oral malodor, discomfort, difficulties eating or speaking from dry mouth complications. They are applied by either a spray or gel to the user's mouth. MedActive Oral Gel and Spray are nonsterile ready to use devices to be used as needed or directed by a health care professional.

MedActive Oral Gel and Spray are equivalent to Boitene Moisturizing Mouth Spray and GC Moisturizing Gel in their intended use. All products are artificial saliva agents designed for relief from dry mouth symptoms.

Indications for Use

Primary Predicate Device - Biotene Moisturizing Mouth Spray

- The Biotene Oral Balance Gel, Biotene Dry Mouth Oral Rinse and Biotene Moisturizing Mouth Spray intended use is to relieve the symptoms of dry mouth, refresh, moisturize, clean, soothe oral irritation and lubricate oral dryness.

Reference Predicate Device - GC Moisturizing Gel

- **GC** Oral Moisturizing Gel is designed to provide comfort for individuals suffering from dry mouth. It is recommended to be used for people who may experience difficulties in eating, speaking or are suffering from discomfort due to dry mouth. **GC** Oral Moisturizing Gel is indicated for the relief of dry mouth symptoms, to provide a protective coating inside the mouth, and help to control bad breath.

Reference Predicate Device - Laclede Oral Balance Liquid/Gel

- Laclede Oral Balance Liquid/ Gel is a refreshing Gel and Liquid that quickly diminishes dry discomfort, mouth odors and other symptoms of a dry mouth.

MedActive Oral Gel and Spray

1. Provides symptom relief from Dry Mouth and low saliva including:

- Oral discomfort
- Mucosal soft tissue dryness
- Oral side effects of illness, therapies, and medications

2. Soothes moistens and lubricates
3. Hydrates soft tissue

All claims of all three devices are similar in nature and are for the relief of dry mouth symptoms and/or oral malodor.

Technological Characteristics

The chemical compositions of MedActive Oral Gel and Spray are similar to the predicate devices. These products contain ingredients such as water, VP/VA copolymer, sodium carboxymethylcellulose, flavorings, sweeteners, glycerol and various thickening agents. The combination of these ingredients provides a pleasant flavor, lubrication of the oral environment when used.

The mode of action of MedActive Oral Gel and Spray are substantially equivalent to the predicate devices.

Summary of Physical Tests

Desorption Testing:

1.4g of each product was placed on a weighing dish and weighed followed by incubation at 37 degrees Celsius for 2 hours. A value obtained by dividing the weight change by the initial weight in terms of percentage was designated as moisture desorption degree. The result of the desorption testing shows that MedActive Oral Relief Gel and MedActive Oral Relief Spray perform similar to the predicate devices.

Mean Percent Loss

Product	**Original Weight (g) - Exp 1, 2**	**Weight Loss (g) - 1, 2**	**Percent Moisture Desorbed (%)- 1, 2**
Biotene Spray (U4E291)	0.399, 0.400	0.152, 0.140	38.1, 35.0
GC Gel (040109M)	0.390, 0.404	0.068, 0.056	17.4, 13.9
MedActive Spray (4077)	0.394, 0.396	0.224, 0.229	56.9, 57.8
MedActive Gel (2661015)	0.411, 0.397	0.141, 0.133	34.3, 33.5

Rheology Testing:

A Rheology study was performed to establish the similarity in the viscosity and rheological behavior of predicate devices compared to MedActive Oral Relief Gel and Spray. The results of the rheological evaluation demonstrate the MedActive Oral Relief Gel and Spray exhibits viscosity and rheological behavior in equivalence to the predicate devices.

Shelf Life Testing:

MedActive Oral Relief Gel and Spray were evaluated for physical characteristics using rheology and desorption testing methods to determine shelf life. The results of these rheology and desorption tests show that MedActive Oral Relief Gel and Spray exhibit similar form and function after three years of real time aging and result in a three year shelf life.

Biocompatibility Testing:

Although MedActive Oral Gel and Spray are limited exposure mucosal membrane devices and do not require biocompatibility testing, Biocompatibility was completed for MedActive Oral Gel. The results from Acute Toxicity, Oral, Eye, and skin Irritation testing show biocompatibility results in accordance with ISO 10993.

pH Testing:

MedActive Oral Relief Gel and Spray were tested for pH using a Fischer Scientific Accumet AB15 pH meter paired with a Thomas Scientific Orion Ross Sure Flow Electrode. The electrode was specifically chosen to provide faster stable readings for gel type samples. The electrode was prepared according to manufacturer's specifications and standardized with VWR standard buffers at pH = 4, 7, 10. All samples were transferred (4 - 7 ml) into polypropylene 10 ml bottles from their original containers. All MedActive samples came from previously unopened containers. The results of the pH testing shows that MedActive Oral Relief Gel and MedActive Oral Relief Spray perform similar to the predicate devices.

Spray	MedActive Samples	pH Results		Predicate Devices	pH Stated
	VM 4077-1	5.78		Biotene Moisturizing Mouth Spray	6.2-7.1
	VM 4077-2	5.76			
Gel					
	OC266-1	5.35		GC Moisturizing Gel	7.2
	OC266-2	5.36		Laclede Oral Balance Liquid/ Gel	5.6

Discussion of Differences

In particular, the variations in formula/composition for MedActive Oral Gel and Spray from the predicate devices are as follows:

- **Solvent:** The main solvent in the current devices are water and a smaller quantity of propylene glycol (a GRAS ingredient) ore EDTA. The predicate devices use water, PEG- 60 and polyglycerol. The predicate devices use PEG-60 or Polyglycerol as a solvent but these ingredients also serve as humectants and rheology modifiers.
- **Mucoadhesive Agents:** Poloxamer 407 and dimethicone emulsions (Ultramulsion ®) was used as the mucoadhesive over Polyvinyl Alcohol (VP/VA), due to its specific development as a surfactant by its manufacturer Whitehill Technologies. Ultramulsion (poloxamer 407 and dimethicone) works as a surfactant that can be retained in the mouth for a period of time to create a smooth, slick feeling. Carboxymethylcelulose (CMC) is also used as a mucoadhesive, as in some predicate devices. While present, these combinations will act as a lubricant and maintain a moist mouth feel for the patient as shown by desorption testing.
- **Rheology Modifiers**: Cellulose gum (carboxymethylcellulose, or CMC) was chosen as a thickener/rheology modifier for the gel based on its significant history of use in dental, oral care and food products. Xanthan gum was chosen for the spray for similar reasons. The resulting viscosity in MedActive Gel and Spray are similar in nature to the predicate devices.
- **Flavoring, Aromas, Sweeteners**: The flavorings in MedActive Gel and Spray are similar in nature to the predicate devices although the specific flavor may differ based on stated label flavor. All devices use aqueous solutions and a sweetener such as xylitol, sorbitol or sodium saccharin as the sweetener.
- **Preservatives**: Potassium sorbate and methylparaben are used as preservatives in MedActive Gel while predicate devices GC Gel and Laclede Gel used ethyl phydroxybenzoatepotassium, soduim citrate and sorbic acid, benzoic acid, lactoperoxidase and lyzome, as preservatives respectively. Potassium sorbate and xylitol are used in MedActive Spray as preservatives and reference device Biotene Spray uses sodium Benzoate, methylparaben, polyparaben, and cetyl- pyridiniumchloride. These ingredients are GRAS and commonly used in dental, oral and food products as

preservatives. In addition, Xylitol, sugar and other sugar substitutes have been shown to act as preservatives in high concentrations (Int J Cosmet Sci. 2011 Oct; 33(5):391-7).

- **pH** - The pH of artificial saliva products in category LFD range from neutral to slightly acidic depending upon the device. The normal pH range for saliva is considered to be 5.6 to 7.9, according to the International Journal of Drug Testing. MedActive has chosen to use preservatives which result in slightly more acidic pH than the predicate devices, and has done so in order to maintain the integrity of its gel and spray against any adventitious organisms. MedActive Gel and Spray have a pH range of 5.35-5.78. Although this pH is slightly more acidic than some predicate devices (and within the range of one reference device) both have low titratable acidity.

Function	**GC Moisturizing Gel Ingredient** K101346	**Biotene Moisturizing Mouth Spray Ingredient** K123731	**Laclede Oral Balance Gel** K061331	**MedActive Oral Relief Gel**	**MedActive Oral Relief Spray**
Solvent	Water	Purified Water	Butylene glycol, water	Water, Propylene glycol	Water, EDTA
Mucoadhesives	Sodium carboxymethyl - cellulose,	VP/VA copolymer,	Hydroxyethylcellulose, Sodium polyacrylate	Poloxamer 407, Dimethicone, Cellulose gum	Poloxamer 407, Dimethicone
Rheology Modifiers	Carrageenan	Glycerin, hydrogenated castor oil, xanthan gum,PEG-60	Polyacrylic acid, Hydroxyethylcellulose	Cellulose gum	Xanthan gum, glycerin,
Humectant	Polyglycerol	Glycerin	Sodium polyacrylate	Glycerin	Glycerin
Flavoring, aromas, sweeteners	Xylitol, Flavoring	Xylitol, sodium saccharin, Flavoring	Xylitol, Hydrogenated Starch Hydrolysate, Glycerol	Sorbitol, sodium saccharin, flavoring	Xylitol, Sodium Saccharin, Flavoring
Preservatives	Ethyl p-hydroxybenzoate, sodium citrate	Sodium Benzoate, methylparaben, polyparaben, cetyl-pyridiniumchloride	Sorbic acid, Benzoic acid, Lactoperoxidase, Lysozyme	Potassium Sorbate, methylparabn	Xylitol, potassium sorbate
Delivery method	Tube with orifice for dispensing	Bottle with spray nozzle	Tube with orifice for dispensing	Tube with orifice for dispensing	Bottle with Spray nozzle
Packaging size	40 g tube	1.5 fl oz	1.5 oz tube	0.5 oz	1 fl oz
pH	7.2	6.2-7.1	5.6	5.35-5.36	5.76-5.78

- All other variations in the formula/composition are concentration and volume variations of common ingredients to allow proper dispensing and use of the product and do not affect the function, indications, or equivalency of the product.

In summary, these differences in formulation to the predicate devices do not alter the function, indications, or substantial equivalency of the products.

In addition:

- Any new components/ingredients are designated GRAS ingredients, food additives or have a significant history of use in dental & medical or food applications.
- All components of the product have been manufactured using standardized and industry accepted state of the art production methods.
- All components of the product have been tested using standardized and industry accepted state of the art test methods.
- The products have been tested using standardized and industry accepted state of the art test methods.

Description of Substantial Equivalence

The chemical components in MedActive Oral Gel and Spray have been used in predicate devices, are listed as GRAS ingredients, are approved food additives/ingredients, or a combination these conditions. We believe these facts well support the compatibility of MedActive Oral Gel and Spray, and that the applicant devices are substantially equivalent to the predicate devices properties, intended use and composition.

Substantial Equivalence Comparison Chart

Product Name	**PREDICATE DEVICE Biotene® moisturizing mouth Spray (K123731)**	**PREDICATE DEVICE GC® oral moisturizing GEL (K10134)**	**Predicate Device Laclede® Oral Balance Gel (K061331)**	**Med*Active*® Oral Relief GEL**	**Med*Active*® Oral Relief Spray**
Method of Use	Ready to Use	Ready to Use	Ready to Use	Ready to Use	Ready to Use
No. of Application/day	Take as needed	Take as needed	Take as needed	Take as needed	Take as needed
Claim	Symptomatic Relief/treatment of Xerostomia	Symptomatic Relief/treatment of Xerostomia	Symptomatic Relief/treatment of Xerostomia	Symptomatic Relief/treatment of Xerostomia	Symptomatic Relief/treatment of Xerostomia
Area of Use	Oral Cavity	Oral Cavity	Oral Cavity	Oral Cavity	Oral Cavity
Disease State	Xerostomia	Xerostomia	Xerostomia	Xerostomia	Xerostomia
Type of Product	Spray	Gel	Liquid/ Gel	Gel	Spray
Presentation	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile

Information provided in this submission confirms the substantial equivalence to the predicate devices with common indications.

Conclusion Statement

MedActive Oral Gel and Spray are a mouth gel and a mouth spray respectively for use in patients that are suffering from dry mouth symptoms. They will coat the inside of the mouth for a short period of time and help create relief from oral malodor, difficulty speaking or eating or general discomfort caused by dry mouth. Their semi viscous formulas create a smooth moist coating on oral tissues as well as providing a pleasant flavor to the user. When compared to the predicate devices and other existing mouth moisturizers and dry mouth products, MedActive Gel and Spray are substantially equivalent.

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