MAY 3 0 2013

5. 510(k) Summary

Submission Application and Correspondence

Name of Device: **OraMoist[R] Patches for Dry Mouth**

Trade/Proprietary/Model Name: **OraMoist[R] Patches for Dry Mouth**
Common or Usual Name: Saliva, Artificial
Classification Names: Dental; Saliva, Artificial

Devices to Which New Device is Substantially Equivalent

Company	Device	K Number
Scandinavian Formulas	SalivaSure Tablets	K051409

Device Description

OraMoist[R] Patches for Dry Mouth is formulated as an oral tablet that adheres to soft tissues of the mouth and dissolves slowly moisturizing the buccal cavity for hours. The tablets are packaged individually in low density polyethylene foil. Each tablet consists of a mixture of electrolytes, natural lubricants, flavoring agents, and enzymes, and an adherent polymer.

Statement of Intended Use

OraMoist[R] Patches for Dry Mouth promotes lubrication of the oral mucosa that may be dry due to side effects of medication, chemo or radiation therapy, or as a symptom of Sjogren's syndrome, or because of oral inflammation. **OraMoist[R] Patches for Dry Mouth** provides temporary relief for dry mouth.

OraMoist[R] Patches for Dry Mouth is intended for Over-The-Counter (OTC) use

Summary of Technological Characteristics of the Device Compared to the Predicate Devices

The subject device (**OraMoist[R] Patches for Dry Mouth**) is a time-released patch that adheres to the oral mucosa. The adhesion is achieved by the addition of an approved biodegradable polymer to the surface of one side of the patch (tablet). The inactive ingredients of the patch provide a means for slow dissolution of the active ingredients (electrolytes, natural lubricants, flavoring agents, and enzymes) responsible for promoting lubrication of the oral mucosa. The predicate device (**SalivaSure**) consists of similar components to promote lubrication of the oral mucosa, however, the delivery is in the form of a lozenge which is unfixed in the oral cavity. OraMoist[R] Patch for Dry Mouth dissolves slowly moisturizing the buccal cavity for hours compared to the predicate device whose label recommends 1 lozenge per hour for severe dry mouth.

Substantial Equivalence Comparison Chart

Product Name	OraMoist[R]	SalivaSure
Method Of Use	Ready to Use	Ready to Use
No. Applications/day	Take as needed	Take as needed
Claim	Symptomatic Relief	Symptomatic Relief
Area of Use	Oral Cavity	Oral Cavity
Disease State	Xerostomia	Xerostomia
Type of Product	Lozenge	Time-release patch
Presentation	Non-sterile	Non-sterile

Tests and Conclusions

In Vitro erosion time (standard USP dissolution test) and clinical investigations in patients with xerostomia have been conducted with **OraMoist[R] Patches for Dry Mouth.**

In conclusion, **OraMoist[R] Patches for Dry Mouth** is substantially equivalent to the predicate device based on components, claims, and intended use with the mechanism of action (adherence to the oral mucosa) for time-release patch differentiating **OraMoist[R] Patches for Dry Mouth** from the predicate device lozenge form.

Correspondence

Quantum, Inc.
754 Washington Street
Eugene, Oregon 97401
541-345-5556
Contact Person: Eve McClure, President

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

May 30, 2013

Quantum, Incorporated
C/O Mr. Fred Ma
Medical Quality International, Limited Liability Company
7195 Longview Drive
CLEVELAND OH 44139

Re: K122663
Trade/Device Name: OraMoist[R] Patches for Dry Mouth
Regulation Number: Unclassified
Regulation Name: Artificial Saliva
Regulatory Class: Unclassified
Product Code: LFD
Dated: January 14, 2013
Received: April 22, 2013

Dear Mr. Ma:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -S, 0.9.2342.19200300.100.1.1=13000879
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Susan Runner, DDS, MA

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Device Name: **OraMoist® Patches for Dry Mouth**

Indications for Use:

OraMoist® Patches for Dry Mouth promotes lubrication of the oral mucosa that may be dry due to side effects of medication, chemo or radiation therapy, or as a symptom of Sjogren's syndrome, or because of oral inflammation. **OraMoist® Patches for Dry Mouth** provides temporary relief for dry mouth.

Prescription Use _____ AND/OR Over-The-Counter Use ____X___

(Part 21 CFR 801 Subpart D) (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)

Digitally signed by Mary S. Runner -S
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122663