K091419

5. 510(k) Summary

AUG 2 8 2009

Submission Date: 12 May 2009

Company Name: The Procter and Gamble Company

Company Address: Mason Business Center
8700 Mason-Montgomery Road
Mason, OH 45040

Contact Person: Richard J. Cooke, PhD
The Procter and Gamble Company
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Device Information:

Trade Name: Vicks Powershot Dry Throat and Mouth Relief

Common Name: Artificial Saliva Device

Classification: Unclassified

Device Description: Vicks Powershot Dry Throat and Mouth Relief is available for application either as a spray or as a bulk liquid, the latter using a dispensing cup. It is a device intended for over-the-counter (OTC) consumer use. The device delivered as a spray form will be packaged in a 1.01 Fl.Oz. (30 mL) polyethylene terephthalate (PET) plastic bottle and will be dispensed from the bottle via a positive displacement pump. The device delivered using a dispensing cup will be packaged in a 6 Fl.Oz (177mL) PET plastic bottle and will be dispensed via a polypropylene dispensing cup. The device is a clear liquid and contains polymers, including carboxymethylcellulose (CMC) that is known to coat and lubricate, as well as components that function as humectants and solvents. The device is preserved and lightly flavored for improved taste. Upon application the device coats and lubricates the mucus membrane of the mouth and oropharynx thereby providing immediate relief of dryness. The device thus functions as an artificial saliva device. See Table 3 for device component listing.

Intended Use: Vicks Powershot Dry Throat and Mouth Relief is intended to provide immediate and effective relief of dry throat and dry mouth by coating, moistening and lubricating.

Technological Characteristic:

The Vicks Powershot Dry Throat and Mouth Relief device is applied to the mucus membrane of the mouth and oropharynx either as a spray or as a bulk liquid using a dispensing cup to coat and lubricate the surface. By coating, moistening and lubricating it treats dry mouth and dry throat and provides immediate relief.

Comparison to Predicate Device:

Vicks Powershot Dry Throat and Mouth Relief device is similar to other medical devices. Like the Moi-Stir™, Throat Moi-Stir™ and Saliva Substitute™ devices, Vicks Powershot Dry Throat and Mouth Relief is a ready to use spray or liquid and can be used as often as needed. Like the Moi-Stir, Throat Moi-Stir and Saliva Substitute devices, Vicks Powershot Dry Throat and Mouth Relief has the same intended use and the same or similar technological characteristics. All devices contain CMC, similar humectants and solvents. Upon application to the throat all devices coat, lubricate and moisten to provide immediate relief of dry mouth and dry throat.

The safety and effectiveness evaluations based on biocompatibility and performance data provided in this 510(k) demonstrate that Vicks Powershot Dry Throat and Mouth Relief device is substantially equivalent to the cited predicate devices.

Product Name	Company	Class	Intended use
Moi-Stir, K810157	Kingswood Laboratories, Inc.	Unclassified	For the relief of dry mouth and dry throat
Throat Moi-Stir, K840807	Kingswood Laboratories, Inc.	Unclassified	For the relief of dry throat
Saliva Substitute, K822971	Roxane Laboratories, Inc.	Unclassified	For immediate and effective relief of dry mouth and dry throat by moistening and lubricating.

Conclusion:

The data provided for Vicks Powershot Dry Throat and Mouth Relief device support the conclusion that it is substantially equivalent to the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

The Procter & Gamble Company
c/o Richard J. Cooke
Senior Regulatory Affairs Manager
Mason Business Center
8700 Mason-Montgomery Rd.
Mason, OH 45040-9462

AUG 2 8 2009

Re: K091419
Trade/Device Name: Vicks Powershot Dry Throat and Mouth Relief
Regulation Number: Unclassified
Regulation Name: Saliva, Artificial
Regulatory Class: Unclassified
Product Code: LFD
Dated: July 13, 2009
Received: July 23, 2009

Dear Mr. Cooke:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091419

4. Indications for Use Statement

510(k) Number (if known): TBD

Device Name: Vicks Powershot Dry Throat and Mouth Relief

Indications For Use:

Vicks Powershot Dry Throat and Mouth Relief Spray - For immediate and effective relief of dry throat and dry mouth by coating, moistening and lubricating.

Vicks Powershot Dry Throat and Mouth Relief Liquid – For immediate and effective relief of dry throat and dry mouth by coating, moistening and lubricating.

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 if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K091419