K062653

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5. 510(k) Summary

October 23, 2006

OCT 27 2006

1. Submission Applicant & Correspondent:

Name:	Parnell Pharmaceuticals, Inc.
Address:	1525 Francisco Blvd., Ste. 15 San Rafael, CA 94901
Phone:	(415)256-1800
Fax:	(415)256-8099
Contact Person:	Francis Parnell, M.D. – President

2. Name of Device:

Trade/Proprietary/Model Name:	MouthKote Oral Moisturizer
Common or Usual Name:	MouthKote Oral Moisturizer
Classification Names:	Dental: Saliva, Artificial
	Dental: Saliva, Artificial

3. Regulatory Information:

Device Class:	Unclassified
Product Code:	LFD

4. Devices to which new device is substantially equivalent:

1. Laclede, Inc.	Oral Balance cleared in K061331
2. Inpharma AB	Caphasol cleared in K991938
3. Gebauer Company	Salivart cleared in K981693
4. Sinclair Pharmaceuticals	Salinum/Oraclair cleared in K024148
5. Laboratoires Carilene S.A.S.	TGO Spray cleared in K051812

5. Device Description:
MouthKote is an artificial saliva substitute which contains moisturizers, polysaccharides and flavones that have lubricating and moistening properties. It contains patented Yerba Santa extract which has a FDA GRAS number and FEMA number. Products are supplied in 5ml tube, 2 fluid oz. and 8 fluid oz. bottles.

6. Intended Use of the Device:
A pleasant tasting solution that diminishes dry mouth discomfort, mouth odors and other symptoms of a dry mouth. MouthKote has the same intended use/indications as the predicate devices:

5. 510(k) Summary

Laclede Inc. Oral Balance
Laboratoires Carilene TGO Spray
Inpharma AB Caphasol
Gebauer Company Salivart
Sinclair Pharmaceuticals Salinum/Oraclair

Please refer to the table below.

7. Summary of Technological Characteristics of the Device compared to the Predicate Devices:

Substantial Equivalence Comparison Chart

Product	MouthKote	Oral Balance	TGO Spray	Caphasol	Salivart	Salinum/ Oraclair
Intended Use	Symptomatic treatment of xerostomia	Symptomatic treatment of xerostomia	Symptomatic treatment of xerostomia	Symptomatic treatment of xerostomia	Symptomatic treatment of xerostomia	Symptomatic treatment of xerostomia
Method of Use	Ready to use liquid	Ready to use liquid and gel	Ready to use spray	Mix parts A & B ampoules	Ready to use spray	Ready to use ampoules
Applications per Day	As needed	As needed	As needed	As needed	As needed	As needed
Disease State	Xerostomia	Xerostomia	Xerostomia	Xerostomia	Xerostomia	Xerostomia
Area of Use	Oral cavity	Oral cavity	Oral cavity	Oral cavity	Oral cavity	Oral cavity
Type of Product	Solution	Solution	Solution	Solution	Solution	Solution
Presentation	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile

8. Tests and Conclusion:
The Mouthkote formulation has been shown to be safe and effective for its intended over-the-counter use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Francis W. Parnell
President
Parnell Pharmaceuticals, Incorporated
1525 Francisco Boulevard, Suite 15
San Rafael, California 94901

OCT 27 2006

Re: K062653
Trade/Device Name: MouthKote Oral Moisturizer
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: LFD
Dated: October 23, 2006
Received: October 24, 2006

Dear Dr. Parnell:

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.

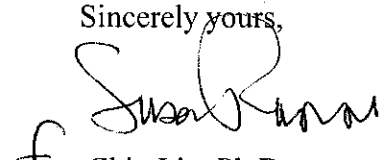
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062653

Indications for Use

510 (k) Number: K062653

Device Name: MouthKote Oral Moisturizer

Indications For Use: Relieves dry mouth conditions

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)

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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