JUL 25 2006

Laclede, Inc.
HEALTHCARE PRODUCTS DIVISION
2103 East University Drive, Rancho Dominguez, CA 90220
Phone: (310) 605-4280 • Fax: (310) 605-4288 • http: //www.laclede.com

K061331

510(k) Summary

May 8, 2006

1. Submission Applicant & Correspondent:

Name:	Laclede, Inc.
Address:	2103 E. University Dr. Rancho Dominguez, Ca 90220
Phone No.:	(310) 605-4280
Contact Person:	Michael Pellico, President

2. Name of Device: **ORAL BALANCE GEL AND LIQUID**

Trade/Proprietary/Model Name:	**ORAL BALANCE GEL AND LIQUID**
Common or Usual Name:	Dental: Saliva, Artificial
Classification Names:	Dental: Saliva, Artificial

3. Regulatory Information:

Device Class:	Unclassified
Product Code:	LFD

4. Devices to which new device is substantially equivalent:

Inpharma AB:	Caphasol cleared in K991938
Gebauer Company:	Salivart cleared in K981693
Sinclair Pharmaceuticals	Salinum or Oraclair cleared in K024148
Laboratoires Carilene S.A.S.	TGO Spray cleared in K051812

5. Device Description:

Oral Balance is an artificial saliva substitute which contains moisturizers, amino acids, milk proteins that have lubricating and moistening properties, it also contains patented salivary enzymes. Product is supplied in 1.5 oz PET bottle and tube.

K18
DE
unclassified

Laclede, Inc.
HEALTHCARE PRODUCTS DIVISION
2103 East University Drive, Rancho Dominguez, CA 90220
Phone: (310) 605-4280 • Fax: (310) 605-4288 • http: //www.laclede.com

6. Intended Use of the Device:

A refreshing Gel and Liquid that quickly diminishes dry discomfort, mouth odors and other symptoms of a dry mouth.

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

Substantial Equivalence Comparison Chart

Product	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
Method of Use	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
Disease State	Xerostomia	Xerostomia	Xerostomia	Xerostomia	Xerostomia
Area of Use	Oral Cavity	Oral Cavity	Oral Cavity	Oral Cavity	Oral Cavity
Type of Product	Lipid solution	Lipid solution	Electrolyte solution	Electrolyte solution	Lipid solution
Presentation	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile

8. Tests and conclusion:

Oral Balance formulation has been shown in studies, including tests for acute oral toxicity, skin and mucous membrane irritation, acute eye irritation and preservative effectiveness to be safe and effective for its indented use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Michael A. Pellico
President
Laclede, Incorporated
2103 East University Drive
Rancho Dominguez, California 90220

JUL 25 2006

Re: K061331
Trade/Device Name: Oral Balance Liquid and Gel
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: LFD
Dated: May 8, 2006
Received: May 12, 2006

Dear Mr. Pellico:

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.

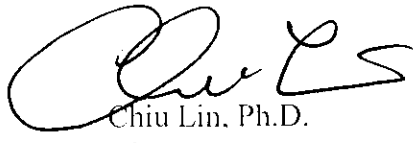
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number (if known): K061331

Device Name: Oral Balance Liquid and Gel

Indications For Use:

A Refreshing Gel and Liquid that quickly diminishes dry discomfort, mouth odors, and other symptoms of a Dry Mouth.

Prescription Use ___ AND/OR Over-The-Counter Use ✓
(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)

Robert S Beck DDS for Dr Susan Runner

(Division Sign-Off)

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

510(k) Number K061331