K041563

AUG 27 2004

H. 510(k) Summary

1. Submission Applicant & Correspondent:

Name: GlaxoSmithKline Consumer Healthcare, L.P.

Address: 1500 Littleton Road

Parsippany, NJ 07054-3884

Phone No.: (973) 889-2566

Contact Person: Anthony Amitrano, U.S. Director Regulatory Affairs

anthony.g.amitrano@gsk.com

2. Name of Device: OASIS®

Trade/Proprietary/Model Name: OASIS® Dry Mouth Relief Discs OR
OASIS® Mouth Moisturizing Discs

3. Devices to Which New Device is Substantially Equivalent:

Gebauer Company: Salivart cleared in 510(k) K981693

Sinclair Pharmaceuticals: SST cleared in 510(k) K023046

Sinclair Pharmaceuticals: Salinum or Oraclair cleared in 510(k) K024148

4. Device Description:

OASIS® is a disc that is allowed to dissolve slowly in the mouth. The product contains a lubricating polymer, with other ingredients to produce a pleasant flavored disc. The discs are presented in containers of various counts.

5. Intended Use of the Device:

Rx:

Under the supervision of a healthcare professional, OASIS® dry mouth relief discs have been formulated for the relief of chronic and temporary xerostomia (dry mouth), which may be a result of disease such as Sjogren's Syndrome, oral inflammation, medication, chemo or radiotherapy, stess or aging.

Over-the-counter:

OTC labeling stipulates that OASIS® mouth moisturizing discs have been specially formulated for the relief of dry mouth symptoms such as difficulties in swallowing, speech, and changes in taste. These symptoms may be brought on by disease, stress, aging or medication.

6. Summary of the Technological Characteristics of the Device Compared to the Predicate Devices:

OASIS® has the same intended use/indications as the predicate devices Gebauer Company Salivart, Sinclair Pharmaceuticals SST, and Sinclair Pharmaceuticals Salinum or Oraclair and is described in the following table.

Product Name	OASIS	Salivart	SST	Salinum or Oraclair
Method of Use	Ready to use	Ready to use	Ready to use	Ready to use
# of Applications per Day	Take as needed	Take as needed	Take as needed up to 16 tablets per day	Take as needed
Claim	Symptomatic treatment of xerostomia	Symptomatic treatment of xerostomia	Symptomatic treatment of xerostomia	Symptomatic treatment of xerostomia
Area of Use	Oral cavity	Oral cavity	Oral cavity	Oral cavity
Disease State	Xerostomia	Xerostomia	Xerostomia	Xerostomia
Type of Product	Disc	Solution	Tablet	Solution
Presentation	Non sterile	Non sterile	Non sterile	Non sterile

7. Tests and Conclusions:

Functional and performance evaluation has been conducted to assess the safety and effectiveness of OASIS® discs. All results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2004

Mr. Anthony G. Amitrano
Director, U.S. Regulatory Affairs
GlaxoSmithKline Consumer Healthcare, L.P.
1500 Littleton Road
Parsippany, New Jersey 07054-3884

Re: K041563
Trade/Device Name: OASIS® Dry Mouth Relief Discs OR Mouth Moisturizing Discs
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: LFD
Dated: June 9, 2004
Received: June 11, 2004

Dear Mr. Amitrano:

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.

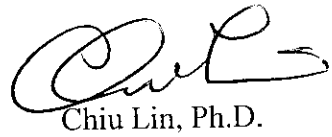
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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/dsma/dsmamain.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): K041563

Device Name: OASIS® Dry Mouth Relief Discs OR Mouth Moisturizing Discs

Indications For Use:

Under the supervision of a healthcare professional, OASIS® dry mouth relief discs have been formulated for the relief of chronic and temporary xerostomia (dry mouth), which may be a result of diseases such as Sjogren's Syndrome, oral inflammation, medication, chemo or radiotherapy, stress or aging.

OASIS® mouth moisturizing discs have been formulated for relief of dry mouth symptoms such as difficulties in swallowing, speech and changes in taste. These symptoms may be brought on by disease, stress, aging or medication.

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)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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