SECTION 5: 510(K) SUMMARY

1. SUBMITTER INFORMATION

Name: GlaxoSmithKline Consumer Healthcare
Address: 1500 Littleton Road
         Parsippany, NJ 07054-3884
Contact Person: Wendy A. McManus
Telephone/Fax: 973-889-4415
              973-889-2501 (fax)
Date Summary Prepared: May 25, 2010

2. DEVICE NAME

Device Name: Biotène Dry Mouth Oral Rinse
Trade or Proprietary Name: Biotène Dry Mouth Oral Rinse
Common or Usual Name: Saliva, Artificial
Classification Name (if known): Saliva, Artificial

3. IDENTIFICATION OF EQUIVALENCE

Laclede, Inc. Oral Balance Gel cleared in K061331
Laclede, Inc. Oral Balance Liquid cleared in K061331

4. DEVICE DESCRIPTION

Biotène Dry Mouth Oral Rinse is a specially formulated artificial saliva substitute which contain moisturizers, humectants, a protein, and patented salivary enzymes, that collectively have lubricating, moisturizing, soothing, and refreshing properties to relieve & treat the symptoms of Dry Mouth. The liquid products are supplied in PET
Ms. Wendy McManus  
Regulatory Associate  
GlaxoSmithKline Consumer Healthcare (GSKCH)  
1500 Littleton Road  
Parsippany, New Jersey 07054

Re: K101477  
Trade/Device Name: Biotene Dry Mouth Oral Rinse  
Regulation Number:  
Regulatory Class: Unclassified  
Product Code: 76 LFD  
Dated: September 17, 2010  
Received: September 20, 2010

Dear Ms. McManus:  

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 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” (21 CFR 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,

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

Enclosure
### SECTION 4: INDICATIONS FOR USE STATEMENT

<table>
<thead>
<tr>
<th>510(k) Number (if known):</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Name:</td>
<td>Biotène Dry Mouth Oral Rinse</td>
</tr>
<tr>
<td>Indications for Use:</td>
<td>Relieves the symptoms of dry mouth; refreshes, moisturizes, cleans, soothes oral irritation, and lubricates oral dryness.</td>
</tr>
</tbody>
</table>

(Please do not write below this line, continue on another page if needed)

<table>
<thead>
<tr>
<th>Prescription Use</th>
<th>OR</th>
<th>Over-The-Counter Use</th>
</tr>
</thead>
</table>

(Per 21 CFR 801.109)

![Signature and Division Sign-Off]

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: **K101477**
bottles of various sizes, including an 8 oz., 16 oz., and 33.8 oz., and also 15 ml. multilayer laminated foil pouches.

5. STATEMENT OF INTENDED USE

Relieves and treats the symptoms of dry mouth; refreshes mouth odors, cleans, soothes oral irritations, moisturizes, lubricates, and diminishes dry discomfort.

The Indication for Use: Relieves the symptoms of dry mouth; refreshes, moisturizes, cleans, soothes oral irritations, and lubricates oral dryness.

6. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS

Characteristics of the device compared to the predicate devices.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>Biotène Dry Mouth Oral Rinse</th>
<th>Oral Balance Gel</th>
<th>Oral Balance Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTENDED USE</td>
<td>Symptomatic Treatment of Xerostomia</td>
<td>Symptomatic Treatment of Xerostomia</td>
<td>Symptomatic Treatment of Xerostomia</td>
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<tr>
<td>METHOD OF USE</td>
<td>Ready to use liquid</td>
<td>Ready to use gel</td>
<td>Ready to use liquid</td>
</tr>
<tr>
<td>APPLICATION PER DAY</td>
<td>As needed</td>
<td>As needed</td>
<td>As needed</td>
</tr>
<tr>
<td>DISEASE STATE</td>
<td>Xerostomia</td>
<td>Xerostomia</td>
<td>Xerostomia</td>
</tr>
<tr>
<td>AREA OF USE</td>
<td>Oral Cavity</td>
<td>Oral Cavity</td>
<td>Oral Cavity</td>
</tr>
<tr>
<td>TYPE OF PRODUCT</td>
<td>Liquid</td>
<td>Gel</td>
<td>Liquid</td>
</tr>
<tr>
<td>PRESENTATION</td>
<td>Non-sterile</td>
<td>Non-sterile</td>
<td>Non-sterile</td>
</tr>
</tbody>
</table>

7. Discussion and conclusions from the nonclinical and clinical tests

Biotène Dry Mouth Oral Rinse has been shown in non-clinical studies to be safe (Toxicology Assessments), and stable (Stability Studies) for its intended use. It has also been shown in clinical studies to be effective (Use Studies). Biocompatibility is addressed in the Statements of Toxicological Evaluation. No other clinical tests were performed other than a Use Study for this submission.