Non-Confidential Summary of Safety and Effectiveness

April 16, 2003

Mark Abramson
35 Renato Court
Redwood City, CA 94061

Tel-(650) 369-9227
Fax-(650) 369-9241

Official Contact: Mark Abramson, D.D.S.
Proprietary or Trade Name: OASYS -Oral Airway System
Common/Usual Name: Oral Appliance – anti-snoring device
Device: OASYS -Oral Airway System
Predicate Devices: Dr. Keith Thorton - K972061
Snore-Ezzer, LLC – K963063
Marketing Technologies, Inc. – K963616
Nellcor Puritan Bennett, Inc. - K962516

Device Description:

The OASYS ORAL AIRWAY SYSTEM Anti-Snoring Device is composed of:

- Lower tray fitted over the lower teeth.
- Upper shield fitting in front of upper anterior teeth.
- Upper molded splint fitted over upper teeth.
- Connecting mechanism joining upper shield and lower tray.
- Extensions off shield which act as nasal dilators

Intended Use:

Indicated use: The OASYS Oral Airway System is intended to reduce or alleviate snoring and obstructive sleep apnea, OSA.

Target population: Adult patients.
Non-Confidential Summary of Safety and Effectiveness
(continued)
Page 2 of 3
April 16, 2003

Environment of Use: Home and sleep laboratories

Comparison to Predicate Devices:

<table>
<thead>
<tr>
<th>Attribute</th>
<th>OASYS K030440</th>
<th>Breathe EZ K022891</th>
<th>Dr. ‘s Mouthpiece K991948</th>
<th>Marketing T.I. k963063</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intended as an intraoral device</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Intended to reduce or help snoring</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Indicated for use with persons who snore</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Indicated for single patient Multi-use</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Indicated for use at home or sleep laboratories</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Design:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heat sensitive impressible material for fitting to teeth</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Custom fit for each user</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Can be adjusted or Refit</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Placed in user's mouth each evening</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Cleaned daily</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Easily removed from Mouth</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Permits user to breath Through mouth</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Non-Confidential Summary of Safety and Effectiveness
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Page 3 of 3
April 16, 2003

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<tr>
<td>Prevents grinding of Teeth</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Materials:**

- Heat sensitive Impression material: Yes, Yes, Yes, Yes
- Rigid tray: Yes, Yes, Yes, Yes
- Non-Sterile: Yes, Yes, Yes, Yes

**Difference Between Other Legally Marketed Predicated Devices**

The difference between the intended device and predicates is only the design of the device. All of the predicates act as mandibular repositioners. The OASYS has extensions which act as nasal dilators. This difference does not have a significant effect on the safety or effectiveness of the device.

Literature supports the historical significance of oral devices that reposition the mandible and reduce and manage snoring as well as sleep apnea.
Dr. Mark Abramson  
Mark Abramson, D.D.S. Incorporated  
35 Renato Court  
Redwood City, California 94061

Re: K030440  
Trade/Device Name: Oasys Oral Airway System  
Regulation Number: 872.5570  
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea  
Regulatory Class: II  
Product Code: LRK, LWF  
Dated: July 8, 2003  
Received: July 8, 2003

Dear Dr. Abramson:

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,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
510(k) Number (if known): K030440

Device Name: OASYS Oral Airway System

Indications For Use:

OASYS Oral Airway System is intended for use to reduce or elevate snoring and obstructive sleep apnea.

(Signature)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
510(k) Number: K030440

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  ✓ OR Over-The-Counter Use  (Per 21 CFR 801.109)