Section 5: 510(k) Summary

1.0 Submitted By:

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Establishment Registration Number: Pending

Primary Contact:
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2.0 Date Submitted:

December 20, 2006

3.0 Device Name(s):

3.1 Proprietary Names

Plaque Scraper-A Interproximal (between teeth) Plaque Remover

3.2 Classification Name

21 CFR 872.6650 (Massaging pick or tip for oral hygiene)
Product code - JET (Pick, Massaging).
4.0 **Predicate Devices:**

<table>
<thead>
<tr>
<th>Candidate</th>
<th>Predicate</th>
<th>Manufacturer</th>
<th>Docket Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaque Scraper-A Interproximal (between teeth) Plaque Remover</td>
<td>Reach Stim-U-Dent Plaque Remover</td>
<td>Whitehill Manufacturing, Inc.</td>
<td>K963747</td>
</tr>
</tbody>
</table>

5.0 **Intended Use:**

The Plaque Scraper-A Interproximal (between teeth) Plaque Remover is an effective cleansing device, which removes plaque and food from between the teeth as part of a program for good oral hygiene to supplement the regular professional care required for oral health. This product is intended for personal oral hygiene use.

6.0 **Comparison to Predicate(s):**

The following tables show similarities and differences between the predicate identified in Section 4.0 of this summary.

<table>
<thead>
<tr>
<th>Product</th>
<th>Aspect/Characteristic</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaque Scraper</td>
<td>Basic Intended Use</td>
<td>Similar to Stim-U-Dent Plaque Remover</td>
</tr>
<tr>
<td></td>
<td>Basic Instructions for Use</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Provided Non-Sterile</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rigid Material</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Beveled Edge Design</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Contraindications for Use</td>
<td></td>
</tr>
</tbody>
</table>
Differences from the Predicate

<table>
<thead>
<tr>
<th>Product</th>
<th>Aspect/Characteristic</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaque Scraper</td>
<td>Material Composition</td>
<td>The Stim-U-Dent product is a bass wood based product whereas the Plaque Remover is a plastic product.</td>
</tr>
<tr>
<td></td>
<td>Design</td>
<td>The Stim-U-Dent product is a toothpick shaped product with a beveled point on one end whereas the Plaque Remover is designed with an elongated handle for ergonomic convenience and has dual rounded and beveled points on each end.</td>
</tr>
</tbody>
</table>

7.0 **Summary of Performance Data:**

The information in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to devices already in commercial distribution. Equivalence is demonstrated through intended use, materials and design.
Kevin VU, DDS
C/O Mr. Glen Feye
Accurate Consultants, Incorporated
1340 West Pennsylvania Avenue
San Diego, California 92103

Re: K070127
  Trade/Device Name: Plaque Scraper-A Interproximal (between teeth)
  Plaque Remover
  Regulation Number: 21 CFR 872.4565
  Regulation Name: Dental Hand Instrument
  Regulatory Class: I
  Product Code: EMN
  Dated: March 14, 2007
  Received: March 18, 2007

Dear Mr. Feye:

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" (21 CFR 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 (240) 276-3150 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): Unknown

Device Name: Plaque Scraper-A Interproximal (between teeth) Plaque Remover

Indications for Use:

The Plaque Scraper-A Interproximal (between teeth) Plaque Remover is an effective cleansing device which removes plaque and food between the teeth as part of a program for good oral hygiene to supplement the regular professional care required for oral health. This product is intended for personal oral hygiene use.

Prescription Use ✔ AND/OR Over-The-Counter Use __________
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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