### 510(k) Summary - SimpliSeal

1. **Contact Person:** Clark D. vonAhsen  
   Associate, Regulatory Affairs  
   Discus Dental, LLC  
   8550 Higuera Street  
   Culver City, CA 90232  
   310.845.8216 – phone  
   310.845.8647 – fax  
   clarkv@discusdental.com

   **Date of Summary Preparation:** May 28, 2009

2. **Name of Medical Device**

   **Proprietary Name:** SimpliSeal  
   **Common/Usual Name:** Root Canal Sealer  
   **Classification Name:** Resin, Root Canal Filling (KIF)

3. **Substantial Equivalence Determination:**

   Discus Dental, LLC believes that SimpliSeal is substantially equivalent to the following commercially marketed products:

<table>
<thead>
<tr>
<th>Predicate Device</th>
<th>Company</th>
<th>510(k) No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adseal</td>
<td>Meta BioMed Co., LTD</td>
<td>K042769</td>
</tr>
<tr>
<td>AH-Plus</td>
<td>Dentsply Intl.</td>
<td>K960548</td>
</tr>
</tbody>
</table>

4. **Description of Medical Device:**

   SimpliSeal is a root canal sealer delivered in a dual-barrel syringe. This epoxy based resin sealer is easy to use with gutta-percha points and can also be used with established and more recent root canal sealing techniques. SimpliSeal provides permanent obturation of root canals when combined with obturation points.
5. Intended Use:

SimpliSeal is a root canal sealer for the permanent sealing of root canals following established endodontic procedures and may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta percha points).

SimpliSeal is intended for use by qualified healthcare personnel trained in its use.

6. Discus Dental, LLC believes that SimpliSeal is substantially equivalent to the following commercially marketed products:

<table>
<thead>
<tr>
<th></th>
<th>Discus Dental</th>
<th>Meta BioMed Co., LTD</th>
<th>Dentsply Intl.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SimpliSeal</td>
<td>Adseal</td>
<td>AH-Plus</td>
</tr>
<tr>
<td>Labeling</td>
<td>Permanent root canal sealer</td>
<td>Permanent root canal sealer</td>
<td>Permanent root canal sealer</td>
</tr>
<tr>
<td>Intended Use</td>
<td>SimpliSeal is a root canal sealer for the permanent sealing of root canals following established endodontic procedures and may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta percha points). Intended for use by qualified healthcare personnel trained in its use.</td>
<td>For permanent sealing of root canals following established endodontic procedures and may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta-percha points). Intended for use by qualified healthcare personnel trained in its use.</td>
<td>AH PLUS Root Canal Sealer is used for permanent sealing of root canals following established endodontic procedures. Intended for use by qualified healthcare personnel trained in its use.</td>
</tr>
<tr>
<td>Similar Physical Properties</td>
<td>ISO 6876 fluidity, working time, film thickness, radiopacity, solubility &amp; disintegration</td>
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</tr>
<tr>
<td>Design, Construction, Components</td>
<td>Premixed, two part paste, packaged in two component plastic syringe ready to be dispensed and mixed.</td>
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</tr>
</tbody>
</table>
The following physical tests have been completed on SimpliSeal:

- Setting time – per ISO 6876
- Flow – per ISO 6876
- Film thickness – per ISO 6876
- Solubility – per ISO 6876
- Dimensional change following setting – per ISO 6876

The following biocompatibility tests have been completed on SimpliSeal:

- Cytotoxicity – ISO 10993-5
- Acute Systemic Toxicity (oral) – ISO 10993-11
- Irritation – ISO 10993-10
- Sensitivity – ISO 10993-10
- Genotoxicity – ISO 10993-3

All testing is within specification and the device performs as designed. The results demonstrate that the device is safe, effective and performs as well as or better than products that are already legally marketed.
FEB 12 2010

Mr. Clark D. Von Ashen
Associate, Regulatory Affairs
Discus Dental, L.L.C.
8550 Higuera Street
Culver City, California 90232

Re: K093208
Trade/Device Name: SimpliSeal
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KWF
Dated: January 21, 2010
Received: January 22, 2010

Dear Mr. Von Ashen:

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" (21CFR 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/Medical Devices/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,

[Signature]

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
E. Indications for Use Statement

510(k) Number (if known): 1093208

Device Name: SimpliSeal

Indications for Use:

SimpliSeal is a root canal sealer for the permanent sealing of root canals following established endodontic procedures and may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta percha points).

SimpliSeal is intended for use by qualified healthcare personnel trained in its use.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K093208