510(k) SUMMARY

Submitter:
Name: Dentaim Co, Ltd
Address: Room No 401, ACE techno Tower 1st, 197-17, Guro-Dong, Guro-Gu, Seoul, Korea

US Agent:
Name: Won Chul Lee
Address: 1352 Amberlea Dr E, Gahanna Ohio 43230 USA
Phone No: 614-444-0660
E-Mail: wonchullee@hotmail.com

Official Correspondent:
Name: Daesuck Chun
Address: Room No 401, ACE techno Tower 1st, 197-17, Guro-Dong, Guro-Gu, Seoul, Korea
Phone No: +82-2-2109-6380
Fax No: +82-2-2109-6389
E-Mail: hi2chun@hanmail.net

Device Identification
Proprietary Name: Zmatch® Block
Common/Usual Name: Porcelain Powder
Classification Name: Porcelain Powder for Clinical Use
Product Code: EIH
Review Panel: Dental
Regulation Number: 872 6660

Substantially Equivalent Predicate Legally Marketed Devices
The subject device is deemed to be substantially equivalent to those following devices manufactured and currently available in commercial distribution:

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Sagemax Bioceramics-Sagemax Z-Blank</th>
<th>Dentsply-Cercon Base</th>
<th>3M-LAVA Zirconia</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(k) Number</td>
<td>K062695</td>
<td>K013230</td>
<td>K11394</td>
</tr>
</tbody>
</table>
Device Description

Zmatch® Block is a pre-formed machineable dental blank composed of zirconium oxide. Zmatch® Block is available in partially-sintered, in different shapes, and dimensions. Zmatch® Block has two models that are A-type model and B-type model. The difference between A-type and B-type is material composition.

Zmatch® Block is a pre-formed ceramic dental blank intended for CAD/CAM fabrication of zirconia frameworks for all-ceramic dental restorations. Zmatch® Block is designed for manufacturing ceramic dental restorations such as single crowns or bridgeworks. The blank is machined by the customers/dental laboratories on their milling centers or similar equipment using CAD/CAM techniques for design.

Indications for Use

The Zmatch® Block is intended for CAD/CAM fabrication of all-ceramic dental restorations. The Zmatch® Block is used for the manufacturing of inlays, onlays, veneers, crowns and bridges.

Technological Characteristics and Substantial Equivalence

Zmatch® block and predicate devices are identical in intended use and material. Therewith, Zmatch® block and predicate devices are biocompatible and have similar biomechanical strength and properties.

Based on the discussion above, Dentaim Co., Ltd. believes that Zmatch® block is substantially equivalent in comparison with predicate devices.
Mr Daesuck Chun  
Manager  
Dentaim Company, Limited  
Room No 401, ACE Techno Tower 1st  
197-17, Guro-Dong, Guro-Gu Seoul, Korea

Re: K083201  
Trade/Device Name: Zmatch® Block  
Regulation Number: 872 6660  
Regulation Name: Porcelain Powder for Clinical Use  
Regulatory Class: II  
Product Code: EIH  
Dated: October 28, 2008  
Received: October 30, 2008

Dear Mr Chun,

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 Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807 97). For questions regarding postmarket surveillance, please contact CDRH’s Office of Surveillance and Biometric’s (OSB’s) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Ginette Y Michaud, M D
Acting 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): K083201
Device Name: Zmatch® Block

Indications for Use:

The Zmatch® Block is intended for CAD/CAM fabrication of all-ceramic dental restorations. The Zmatch® Block is used for the manufacturing of inlays, onlays, veneers, crowns and bridges.

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)

[Signature]

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

510(k) Number: K083201