K071548

VIII. Premarket Notification 510(k) Summary

AUG 2 1 2007

Submitted by:	Merz Dental GmbH Eetzweg 20 D-24321 Lutjenburg Germany 0 43 81/4 03-4 11 (phone) 0 43 81/4 09-1 07 (fax)
Contact person:	Dr. Med Claudia Bobrowski
Date prepared:	June 1, 2007
Device proprietary name:	Wieland Zeno CAO temporary PMMA disc, tooth-colored
Common name:	PMMA Crown and Bridge Material
Classification name:	Temporary Crown and Bridge Resin (21 CFR 872.3770)
Predicate devices:	artegral® ImCrown, Merz Dental (K061809) Temporary Crown and Bridge Material, Dentsply International (K060293)
Description of the device:	Discs of PMMA in two sizes and three shades for milling into provisional crowns and bridges.
Intended use:	For use as a milling blank in the fabrication of provisional crowns and bridges.
Characteristics:	An ideal material for the fabrication of provisional crowns and bridges because of its strength, ease of milling, dimensional stability, and natural esthetic.
Testing:	Tested for compliance to ISO 3336 and ISO 10993.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 1 2007

Merz Dental GmbH
C/O Mr. Richard G. Hunter
Principal
Washington Regulatory Consultants
5616 Mariola Place, NE
Albuquerque, New Mexico 87111

Re: K071548
Trade/Device Name: Wieland Zeno CAO Temporary PMMA Disc, Tooth-Colored
Regulation Number: 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: August 3, 2007
Received: August 13, 2007

Dear Mr. Hunter:

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.

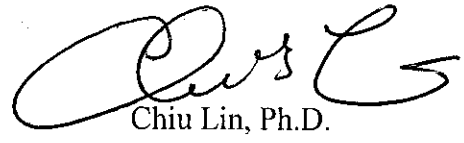
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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" (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/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

V. Indications for Use Statement

510(k) Number: ~~To be assigned~~ K071548

Device Name: Wieland Zeno CAO temporary PMMA disc, tooth-colored

Indications for Use: For use as a milling blank in the fabrication of provisional crowns and bridges.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K071548