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510 (K) – PREMARKET NOTIFICATION

Device	Metoxit CAM-Blanks

K07 2569

510 (k) Summary

OCT 3 1 2007

Submission Correspondent:

Emergo Group, Inc.
1705 S. Capital of Texas Hwy
Suite 500
Austin, TX 78746

Phone: 512-327-9997
Fax: 512-327-9998
Email: iangordon@emergogroup.com
Contact: Ian Gordon
Sr. Vice President

Submission Sponsor:

Metoxit AG
Emdwiesenstrasse 6
CH-8240 Thayngen

Phone: +41 52 645 0101
Email: Stefan.koebel@metoxit.com
Contact: Dr. Wolfram Weber, General Manager

Date summary prepared:

July 31, 2007

Device trade name:

Metoxit CAM-Blanks

Device common name:

CAM-Blanks

Device classification name:

Porcelain Powder for Clinical Use

Legally marketed devices to which the device is substantially equivalent:

K013230, K051462 - Cercon base
K051462 Cercon base colored
K050903 XAWEX G100
K022996 Vita YZ cubes
K051705 Ivoclar ZIRCAD
K052130 Vita AL cubes
K062506 Sirona InCoris AL
K001815 DCS DC-Zirkon

Description of the device:

Metoxit CAM-Blanks are dental ceramics, composed of yttrium-oxide stabilized tetragonal zirconium-oxide polycrystals.

Metoxit CAM-Blanks are designed for the manufacturing of substructures for all-ceramic dental appliances. The dental appliance is machined either by CAD/CAM machining technique or the copying technique, then sintered to full density and strength and for the sole use of the particular patients.

Metoxit CAM-Blanks are designed for the use as single tooth restorations or bridgeworks with up to two pontics in the anterior as well as in the posterior teeth region.

Intended use of the device:

Metoxit blanks are indicated for use as a substructure for porcelain fused ceramic fixed dental restorations.

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Technological characteristics:	The technological characteristics between the predicate and proposed devices are identical. There is no difference in fundamental scientific technology. They are made from the same materials and have the same intended use.
Conclusions:	By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device. There are no significant differences between the Metoxit CAM – Blanks and the predicate devices and therefore, the Metoxit CAM-Blanks do not raise any questions regarding safety and effectiveness. The Metoxit CAM-Blanks, as designed, are as safe and effective as the predicate device, and the device is determined to be substantially equivalent to the referenced predicate devices currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 2007

Metoxit AG
C/O Mr. Ian Gordon
Senior Vice President
Emergo Group, Incorporated
1705 South Capital of Texas Highway
Suite 500
Austin, Texas 78746

Re: K072569
Trade/Device Name: Metoxit CAM-Blanks
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: September 6, 2007
Received: September 12, 2007

Dear Mr. Gordon:

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.

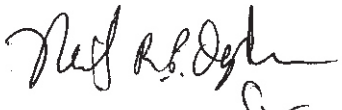
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use Statement

510(k) Number: K072569

Indications for Use:

Metoxit blanks are indicated for use as a substructure for porcelain fused ceramic fixed dental restorations. Limitations are listed in Table 1.

Table 1: Indications of use and maximum number of pontics.

Process chain	Material	Single unit crowns		Bridges, number of pontics	
		Anterior	Posterior	Anterior	Posterior
Porous blank is machined to enlarged framework, then sintered and veneered.	TZP-A	X	X	2	2
	Al-999	X	X	1	-
Dense blank is machined to net-shape framework, then veneered.	TZP	X	X	2	2
	TZP-A	X	X	2	2

X indicated; - not indicated; digits show maximum number of pontics.

All blanks are solely by or on the order of a dental professional. They are not for use by the general public or over-the-counter.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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