Metoxit AG
Dr. Gian-Carlo Gullo
CEO
Emdwiesenstrasse 6
Thayngen, Switzerland CH-8240

August 23, 2018

Re: K170050
Trade/Device Name: Z-CAD Smile
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: May 28, 2018
Received: June 5, 2018

Dear Dr. Gian-Carlo Gullo:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170050

Device Name
Z-CAD Smile

Indications for Use *(Describe)*
METOXIT Z-CAD® smile blanks are indicated for the preparation of full ceramic crowns, inlays, onlays, veneers and 3 unit bridges in the anterior area. All white Z-CAD® smile blanks are indicated to be coloured with Z-CAD® Liquid smile-TC.

The Z-CAD® Liquid smile-TC will be used to dye white pre-sintered zirconia restorations milled from Z-CAD® smile blanks in the dental field.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) Number: **K170050**

Submitter	Metoxit AG Emdwiesenstrasse 6 CH-8240
Contact Person	Dr. Gian-Carlo Gullo (CEO) raqa@metoxit.com Phone: +41 52 6450101 / Fax: +41 52 6450100
Date Prepared	August 23rd 2018
Device	
Name of Device	Z-CAD® smile
Common Name	Powder, Porcelain
Classification Name	Porcelain powder for clinical use
Regulatory Class	II
Product Code	EIH
510(k) Number	K170050
	There were no prior submissions for the subject device.
Primary Predicate Device	Zolid FX, Amann Girrbach, K152383
Reference Devices	DD cubeX^2, Dental Direkt, K150196
	Zenostar MT, Wieland, K152118

Device Description

Z-CAD® smile ceramic blanks are indicated for the production of dental-prosthetic restorations. The blanks named above can be machined with CAM, CAD/CAM or copy milling systems commonly used in dental medical technology to produce dental-prosthetic restorations made from zirconium oxide. This material offers excellent properties with regards to bio-compatibility, stability and aesthetics, which make it the material of choice for the production of restorations for dental crowns, inlays, onlays, veneers, and up to three unit bridges, which in turn combine

the advantages of conventional casting technology and full ceramics. Dental technicians are therefore in a position to offer patients the extra added value when finishing the prosthesis.

Metoxit Z-CAD® smile Blanks also includes Z-CAD® Liquids smile-TC.
Z-CAD® Liquids smile-TC are ready for use water-based products, which are applied to the milled restauration prior to sintering to achieve individual shades. These liquids are specifically formulated for the dyeing of Z-CAD® smile blanks from Metoxit AG.

Indications for Use

METOXIT Z-CAD ® smile blanks are indicated for the preparation of full ceramic crowns, inlays, onlays, veneers and 3 unit bridges in the anterior area. All white Z-CAD® smile are indicated to be coloured with Z-CAD® liquid smile-TC.

The Z-CAD® Liquid smile-TC will be used to dye white pre-sintered zirconia restorations milled from Z-CAD® smile blanks in the dental field.

Comparison of Technological Characteristics with the primary predicate device

Z-CAD® smile Blanks are for the preparation of full ceramic crowns, inlays, onlays, veneers and 3 unit bridges in the anterior area. This is similar to the indication for use stated for the primary predicate device, with the exception that the primary predicate device is also intended for use in the posterior range.

All characteristics of the subject and the primary predicate device are compared in the table on page 02-4:

Chemical Composition and specifications are similar for the subject and the primary predicate device. There are no significant deviations, and therefore no difference in safety and effectiveness.
The material consists of ZrO_2 + HfO_2 + Y_2O_3, Y_2O_3, Al_2O_3 and other Oxides in the subject and the primary predicate device.

The shapes and dimensions are also comparable for Metoxit Z-CAD smile and the primary predicate device. Additionally, the reference devices have been included in this submission to demonstrate equivalence in the range of dimensions. The shapes and dimensions do not influence the safety or the effectiveness.

The defined specifications for Metoxit Z-CAD smile: Flexural Bending Strength, Coefficient of Thermal Expansion, Radioactivity (raw material) and Solubility (acetic acid) have no significant deviations to the primary predicate device. Therefore, there is no difference in safety or effectiveness between the subject and the primary predicate device.

Performance Data

Shelf Life:

Shelf-life for the Z-CAD® smile ceramic blanks was set at 10 years by Metoxit based on the risk assessment of the packaging material, as well as a confirmatory machining test performed on a product stored for more than 10 years.

Biocompatibility testing:

The biological risk assessment was performed based on the chemical composition of the subject device, which is similar to what is historically used for this device type. . The biological risk assessment was performed in accordance to ISO 10993-1. Additionally, a confirmatory cytotoxicity study was performed in accordance to ISO 10993-5.

Bench test for each raw material or product batch:

The proposed Z-CAD® smile was evaluated using the following performance bench testing to confirm the performance characteristics:

Physical properties	**Units**	**Z-CAD® smile pass criteria**	**Testing method***		**Primary predicate device**
Bending strength (biaxial)	MPa	≥ 500	ASTM C1161		> 500
Solubility (acetic acid)	µg/cm2	≤ 100	ISO 6872		< 100
Radioactivity	Bq/kg	≤ 200	GS		< 200

Table for comparison of technical characteristics between subject and primary predicate device

Trade Name	**Z-CAD smile**	**Zolid FX**	
	This submission	**Primary predicate device**	
510(k) number	K170050	K152383	
510(k) submitter/holder	METOXIT	Amann Girrbach	**Evaluation of difference**
$ZrO_2 + HfO_2 + Y_2O_3$	> 99.5	≥ 99.0	Equal or better
Y_2O_3	9.3	9.15 – 9.55	Equal or better
Al_2O_3	0.05	≤ 0.06	Equal or better
Other Oxides	< 0.5	---	Equal or better
Shape	Disks	Disks (U-shape)	Similar, does not influence safety or effectiveness
Dimensions	Various (Diameter: 98.5 ± 0.5 mm Height: 10 to 25 mm)	Various (Diameter: 90x70 mm Height: 12 to 25 mm)	Similar, does not influence safety or effectiveness
Flexural Bending Strength	610 MPa	> 500 MPa	Equal or better
Coefficient of Thermal Expansion	$10*10^{-6/K}$	$10.1 \pm 0.5*10^{-6/K}$	Similar, does not influence safety or effectiveness
Radioactivity (raw material)	< 45 Bq/kg	< 200 Bq/kg	Equal or better
Solubility (acetic acid)	≤ 50 µg/cm^2	< 100 µg/cm^2	Equal or better

Conclusions

All information provided in this premarket notification from Metoxit AG, supports the conclusion that Z-CAD® Smile is found substantially equivalent to the primary predicate device.