DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 21,2015

Amann Girrbach AG
c/o Ms. Rachel Paul
Emergo Europe Consulting
Prinsessegracht 20
The Hague, 2514AP
THE NETHERLANDS

Re: K152383
Trade/Device Name: Ceramill Zolid FX
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: August 24, 2015
Received: August 24, 2015

Dear Ms. Paul:

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 contact 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. 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/MedicalDevices/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,

Erin I. Keith, M.S.
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)*

Device Name
"Ceramill Zolid FX"

Indications for Use *(Describe)*
"Ceramill Zolid FX" preshade are blanks made of zirconium oxide (ZrO_2) for type II, class 5 dental applications in accordance with DIN EN ISO 6872. They are used for manufacturing permanent and removable prosthetic restorations (e.g., crowns and three-unit bridges to the molar region) using CNC milling machines (e.g., Ceramill Motion).

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary

for

"Ceramill Zolid FX"

1. Submission Sponsor

Amann Girrbach AG
Herrschaftswiesen 1
6842 Koblach
Austria
Phone: +49 (7231) 957-260
Fax: +49 (7231) 957-249
Contact: Debora Engel, Regulatory Affairs Manager

2. Submission Correspondent

Emergo Europe Consulting
Prinsessegracht 20
2514AP The Hague
The Netherlands
Cell Phone: +33 (0)6 89 83 16 09
Office Phone: +31 (0) 70 345 85 70
Direct: +31 (0) 70 850 82 49
Fax: +31 (0) 70 346 72 99
Contact: Rachel Paul, Senior Consultant, RA & QA
Email: project.management@emergogroup.com

3. Date Prepared

11 September 2015

4. Device Identification

Trade/Proprietary Name:	"Ceramill Zolid FX"
Common/Usual Name:	Porcelain powder for clinical use
Classification Name:	Powder, Porcelain
Classification Regulation:	21 CFR Part 872.6660
Product Code:	EIH
Device Class:	Class II
Classification Panel:	Dental

5. Legally Marketed Predicate Device(s)

Amann Girrbach America, Inc. Ceramill ZI blanks 510(K) Number K063511.

6. Device Description

Amann Girrbach AG "Ceramill Zolid FX" is an all-ceramic core dental material made of Yttria-Stabilized Zirconium Oxide (zirconia, YSZ). It is provided as a disk shape (U-shape). CAD/CAM fabrication of core material can then be used to produce copings and substrates for fixed all ceramic dental restorations above the gum line. The material is used for the manufacturing of permanent and removable prosthetic restorations (e.g. crowns and three-unit bridges to the molar region). The material is then fired in an oven to harden the ZrO2. The milling and final oven hardening is completed by the customer (the dental technician).

7. Indication for Use Statement

Zirconium-oxide blanks for permanent and removable dental prosthetics.

8. Substantial Equivalence Discussion

The following table compares the "Ceramill Zolid FX" to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	**Amann Girrbach AG**	**Amann Girrbach America, Inc.**	**Significant Differences**
Trade Name	Ceramill Zolid FX	Ceramill ZI	
510(k) Number	K152383	K063511	N/A
Product Code	EIH	EIH	Same
Regulation Number	21 CFR Part 872.6660	21 CFR Part 872.6660	Same
Regulation Name	Porcelain Powder for Clinical Use	Porcelain Powder for Clinical Use	Same
Indications for Use	Zirconium-oxide blanks for permanent and removable dental prosthetics.	Amann Girrbach America, Inc. Ceramill ZI blanks are used in the manufacture of dental prosthetics.	Same. Ceramill ZI blanks are used in the manufacture of dental prosthetics permanent and removable.

Manufacturer	Amann Girrbach AG	Amann Girrbach America, Inc.	Significant Differences
Trade Name	Ceramill Zolid FX	Ceramill ZI	
Applications	- anatomically reduced crown and up to 3-unit bridge frames in the anterior and posterior tooth range, as well as monolithic (fully anatomical) crowns and 3-unit bridges - anatomically reduced bridge frames with a maximum of one connected intermediate units in the anterior and in the posterior region monolithic bridges with a maximum of one connected intermediate units in the anterior and in the posterior region.	- anatomically reduced crown and bridge frames in the anterior and posterior tooth range - bridges frames with a maximum of 3 connected intermediate units in the anterior and 2 connected intermediate links in the posterior region, and a maximum anatomical length of 50mm cantilever bridges with a maximum of 1 bridge pontic (maximum 1 free-end pontic and no further than the second premolar).	Similar with minor variance: exclusion of too long (more than one connected intermediate units) bridge frames for the Ceramill Zolid FX blanks.
Material (wt%)	Zirconia $ZrO_2 + HfO_2 + Y_2O_3 \geq 99.0\%$ Composition: Y_2O_3 9.15 – 9.55 Al_2O_3 ≤ 0.06 HfO_2 < 3 SiO_2 ≤ 0.02 Fe_2O_3 ≤ 0.01	Zirconia $ZrO_2 + HfO_2 + Y_2O_3 > 99.0\%$ Composition: Y_2O_3 4.5 – 5.6 Al_2O_3 < 0.5 HfO_2 < 5 SiO_2 and Fe_2O_3 < 0.5	Similar. All meet ISO 13356
Shapes	Disks (U-shape)	Disks, blocks	Similar. Ceramill Zolid FX only available in U-shape.
Dimensions	various 6 sizes (approx. 90 x 70mm) of different height (12, 14, 16, 18, 20 and 25mm)	various 3 sizes: 2 rectangular (40 x 20 x 16mm, 65 x 30 x 20mm) and 1 round (98 x 20 mm)	Similar. Ceramill Zolid FX only available in U-shape.
Supplied Sterile	No	No	Same
Single Use	Yes	Yes	Same
Sintering Temperature	1450°C – 2 hours	1450°C – 2 hours	Same
Bulk Density	$\geq 6.05\ g/cm^3$	$\geq 6.07\ g/cm^3$	Similar. Both meet ISO 6872
Open Porosity	0%	0%	Same
Grain Size	0.8 µm	≤ 0.6 µm	Similar. Comparable values, no impact on properties
Flexural Bending Strength	>500MPa	≥1200MPa	Difference. Too long (more than 1 connected intermediate units) bridge frames are excluded from Ceramill Zolid FX blanks indications. Both meet ISO 13356
Weibull Modulus	9.54	10.63	Similar. Both meet ISO 13356
Hardness (Vicker's Hardness)	1300 ± 200 HV10	1300 ± 200 HV10	Same
Coefficient of Thermal	$10.1 \pm 0.5 * 10^{-6}/K$	$10.4 \pm 0.5 * 10^{-6}/K$	Similar. Both meet ISO 9396

Modulus of Elasticity	>200GPa	>200GPa	Same
Radioactivity (raw material)	<0.2Bq/g	<0.2Bq/g	Same

The "Ceramill Zolid FX" device shares the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate device. All of the components have been used in legally marketed devices. The formulations have not been changed in ways that may adversely impact safety or efficacy.

9. Non-Clinical Performance Data

Safety and performance of "Ceramill Zolid FX" was shown in accordance with applicable national and international standards. The material complies with ANSI ADA Specification No. 69:2010, *Dental Ceramic*.

Non-clinical testing was performed in order to validate the design against the Company's specified design requirements for physical and chemical properties, as well as flexural strength, and to assure conformance with the consensus design standard ISO 6872:2008. "Ceramill Zolid FX" is classified as Type II Class 5 esthetic dental ceramic.

The disks can be fabricated into various prosthetic dental devices and the zirconia powder conforms to ISO 6872:2008, *Dentistry – Ceramic Materials* and BS EN 1641:2004, *Dentistry, Medical Devices for Dentistry, Materials.* The table below summarizes the results.

Table 5B: Testing performed for the "Ceramill Zolid FX" 510(k) Submission

Test	Conformance to ISO 6872:2008
Flexural Strength (4-point bending test)	The results meeting the predefined criteria as specified in ISO 6872:2008 (E) support a finding of substantial equivalence.
Weibull Modulus	The results meeting the predefined criteria as specified in ISO 6872:2008 (E) support a finding of substantial equivalence.
Vickers Hardness	The results meeting the internal specifications requirements support a finding of substantial equivalence.
Final density	The results meeting the predefined criteria as specified in ISO 6872:2008 (E) support a finding of substantial equivalence.
Thermal Expansion Coefficient (CTE)	The CTE results meeting the predefined criteria as specified in ISO 6872:2008 (E) support a finding of substantial equivalence.
Open Porosity	The results meeting the predefined criteria as specified in ISO 6872:2008 (E) support a finding of substantial equivalence.
Modulus of Elasticity	The results meeting the internal specifications requirements support a finding of substantial equivalence.
Radioactivity	The results meeting the predefined criteria as specified in ISO 6872:2008 (E) support a finding of substantial equivalence.
Cytotoxicity	The results show that the extract of the test material caused no toxicological/biological cell damages and growth inhibition.
Chemical Analysis	The extracts of the material did not contain organic or inorganic detectable substances

The "Ceramill Zolid FX" passed all testing stated above as shown by the acceptable results obtained.

The "Ceramill Zolid FX" complies with the applicable voluntary standards for demonstrating biocompatibility:

- ISO 10993-1: 2010, *Biological Evaluation of Medical Devices --- Part 1: Evaluation and Testing within a Risk Management Process*

- ISO 10993-5: 2009, *Biological Evaluation of Medical Devices --- Part 5: Test for In Vitro Cytotoxicity*
- ISO 10993-12: 2012, *Biological Evaluation of Medical Devices – Part 12: Samples preparation and reference materials*
- ISO 10993-18:2005, *Biological Evaluation of Medical Devices – Part 18: Chemical characterization of the materials*
- ISO 7405:2008, Second Edition, *Dentistry – Evaluation of biocompatibility of medical devices used in dentistry*

Test results show that the extract of the test material caused no toxicological/biological cell damage or growth inhibition. The material is considered as non-cytotoxic and the extracts of the material did not contain organic or inorganic detectable substances.

The "Ceramill Zolid FX" complies with the applicable voluntary standard for risk management, ISO 14971:2007, *Medical devices – Application of risk management to medical devices*. The risk management activities verified that risks have been eliminated or reduced to acceptable levels from a benefit/risk assessment.

The "Ceramill Zolid FX" meets all the requirements for overall design and biocompatibility, and performance testing confirms that the output meets the design inputs and specifications.

10. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device (there have been little to no adverse events reported). The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

The proposed device and the predicate have the same intended use. The technological characteristics are identical or similar.

It has been shown in this 510(k) submission that the difference between the "Ceramill Zolid FX" and the predicate devices do not raise any different questions regarding its safety and effectiveness. The "Ceramill Zolid FX", as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.