DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Amann Girrbach AG
% Rachel Paul
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September 20,2017

Re: K171876
Trade/Device Name: Ceramill Zolid HT+ white
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: July 17, 2017
Received: July 20, 2017

Dear Rachel 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 Industry and Consumer Education (DICE) 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" (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 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 Industry and Consumer Education (DICE) 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,

Susan Runner

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)*
K171876

Device Name
Ceramill Zolid HT+ white

Indications for Use *(Describe)*
Zirconium-oxide blanks for permanent and removable dental prosthetics.

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 (Special 510(k))

Ceramill® Zolid HT+ white

K171876

1. **Submission Sponsor**

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3. **Date Prepared**

26th June 2017

4. Device Identification

Trade/Proprietary Name: Ceramill® Zolid HT+ white

Common/Usual Name: Porcelain powder for clinical use

Classification Name: Porcelain Powder

Regulation Number: 872.6660

Product Code: EIH

Device Class: Class II

Classification Panel: Dental

5. Legally Marketed Predicate Device(s)

K063511, Ceramill® ZI, Amann Girrbach America

6. Indication for Use Statement

Zirconium-oxide blanks for permanent and removable dental prosthetics.

7. Device Description

Amann Girrbach AG Ceramill® Zolid HT+ white is an all-ceramic core dental material made of Yttria-Stabilized Zirconium Oxide (zirconia, YSZ). It is provided as a disk shape (U-shape or round-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. The material is then fired in an oven to harden the ZrO_2. The milling and final oven hardening is completed by the customer (the dental technician).

8. Substantial Equivalence Discussion

The following table compares the modified device Ceramill® Zolid HT+ white to the unmodified predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides detailed information regarding the basis for the determination of substantial equivalence, and supports that the subject device, as modified, does not raise any new issues of safety or effectiveness than the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer	**Amann Girrbach AG**	**Amann Girrbach America, Inc.**	**Device Comparison**

Trade Name	Ceramill® Zolid HT+ white	Ceramill® ZI (Predicate)	
510(k) Number	Unknown	K063511	N/A
Product Code	EIH	EIH	Same
Regulation Number	872.6660	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.	Zirconium-oxide blanks for permanent and removable dental prosthetics.	Same
Conditions of Use	-Anatomically reduced crown and bridge frames in the anterior and posterior tooth range, and monolithic (fully anatomical) crowns and bridges; -Anatomically reduced four to multi-unit bridge frames with a maximum of three connected intermediate units in the anterior region and a maximum of two connected intermediate links in the posterior region; -Monolithic four to multi-unit bridges with a maximum of three connected intermediate units in the anterior region and a maximum of two connected intermediate links in the posterior region; -Cantilever frames and bridges with a maximum of one bridge unit (maximum one free-end pontic and no	-Anatomically reduced crown and bridge frames in the anterior and posterior tooth range, and monolithic (fully anatomical) crowns and bridges; -Anatomically reduced four to multi-unit bridge frames with a maximum of three connected intermediate units in the anterior region and a maximum of two connected intermediate links in the posterior region; -Monolithic four to multi-unit bridges with a maximum of three connected intermediate units in the anterior region and a maximum of two connected intermediate links in the posterior region; -Cantilever frames and bridges with a maximum of one bridge unit (maximum one free-end pontic and no	Same

Manufacturer	**Amann Girrbach AG**	**Amann Girrbach America, Inc.**	**Device Comparison**
Trade Name	**Ceramill® Zolid HT+ white**	**Ceramill® ZI (Predicate)**	
	further than the second premolar).	further than the second premolar).	
Contraindications	-Insufficient tooth-structure availability -Insufficient preparation results -Insufficient oral hygiene -More than two connected bridge units in the posterior region, more than three connected intermediate units in the anterior region -Known incompatibilities with respect to the components -Heavily discolored hard tooth structure -Provisional insertion	-Insufficient tooth-structure availability -Insufficient preparation results -Insufficient oral hygiene -More than two connected bridge units in the posterior region, more than three connected intermediate units in the anterior region -Known incompatibilities with respect to the components -Heavily discolored hard tooth structure -Provisional insertion	Same
Chemical composition (wt%)	-Zirconia : $ZrO_2 + HfO_2 + Y_2O_3 \geq 99.0$ -Composition: Y_2O_3: 6.7 – 7.2 HfO_2: ≤ 5 Al_2O_3: ≤ 0.5 Others oxides: ≤ 1	-Zirconia : $ZrO_2 + HfO_2 + Y_2O_3 \geq 99.0$ -Composition: Y_2O_3: 4.5 – 5.6 HfO_2: ≤ 5 Al_2O_3: ≤ 0.5 Others oxides: ≤ 1	Similar – variance in material does not introduce any new safety or effectiveness concerns. Both materials meet $ZrO_2 + HfO_2 + Y_2O_3 \geq 99.0$.
Shapes	Disks (« U »-shape or round-shape)	Disks (round), blocks (rectangular)	Similar – predicate is available in disks and blocks whereas Ceramill® Zolid HT+ white is available only in disk shape as the block shape used for manual copy milling is no more sold.

Manufacturer	**Amann Girrbach AG**	**Amann Girrbach America, Inc.**	**Device Comparison**
Trade Name	**Ceramill® Zolid HT+ white**	**Ceramill® ZI (Predicate)**	
Dimensions (mm)	-Various -« U »-shape: 90 x 72, in eight different heights (10, 12, 14, 16, 18, 20, 25, 30). -Round-shape: 98 mm of diameter, in eight different heights (10, 12, 14, 16, 18, 20, 25, 30).	-Various -Three sizes: two rectangular (40 x 20 x 16 and 65 x 30 x 20) and one round (98 x 20).	Similar – both are available in various sizes
Supplied sterile	No	No	Same
Single use	Yes	Yes	Same
Sintering Temperature and Duration	1450°C – 2 hours	1450°C – 2 hours	Same – Both meet ISO 6872:2015
Shelf Life	5 years	5 years	Same
Opacity (%)	60.0 ± 1.5%	69.0 ± 1.5%	Different - Ceramill® Zolid HT+ white has a higher translucency (lower opacity) compared to predicate but an equivalent high bending strength.
Flexural bending strength (at 3-point) (MPa) (and Weibull modulus)	1100 ± 150 (≥8)	1200 ± 150 (≥8)	Similar – Both meet ISO 6872:2015 minimum average of 800 MPa. A difference of 100 MPa is not significant. Both are classified dental ceramics of Type II, Class 5 according to ISO 6872:2015.
Flexural bending strength (at 4-point) (MPa) (and	1000 ± 150 (≥8)	1000 ± 150 (≥8)	Same

Manufacturer	**Amann Girrbach AG**	**Amann Girrbach America, Inc.**	**Device Comparison**
Trade Name	**Ceramill® Zolid HT+ white**	**Ceramill® ZI (Predicate)**	
Weibul modulus)			
E-module (GPa)	≥ 200	≥ 200	Same
Thermal expansion coefficient (CTE) (25-500°C) (10^{-6}/K)	10.4 ± 0.5	10.4 ± 0.5	Same
Chemical solubility (µg/cm²)	< 100	< 100	Same
Vickers hardness (HV10)	1300 ± 200	1300 ± 200	Same
Final Density (g/cm³)	≥ 6.05	≥ 6.07	Similar – a difference of 0.02 is not significant. Both meet ISO 6872:2015.
Porosity (%)	0 (no open porosity)	0 (no open porosity)	Same
Grain Size (µm)	≤ 0.6	≤ 0.6	Same
Shrinkage	V (L/W): 22.00 – 24.00% V (H): 21.00 – 24.00% H < 1	V (L/W): 24.50 – 28.00% V (H): 23.50 – 28.00% H < 1	Similar – the difference in shrinkage has no influence on the performance and safety of the blanks. Shrinkage is only a process parameter for the dental lab.
Radioactivity (Bq/g)	≤ 1.0	≤ 1.0	Same

9. Non-Clinical Performance Data

Bench tests confirm that product specifications of the modified device Ceramill® Zolid HT+ white are met. These are equivalent to those of the predicate device. The biocompatibility testing confirm that the modified device Ceramill® Zolid HT+ white is as biocompatible as the predicate. The testing results support that the new zirconia material does not affect the safety and effectiveness of the device as compared to the zirconia material of the unmodified device. Verification testing of the modified device Ceramill® Zolid HT+ white, in accordance with design controls, demonstrated the device meets user needs. Verification testing was performed to the following:

- ISO 6872:2015 – Dentistry – Ceramic Materials
- ISO 13356:2015 - Implants for surgery. Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)
- ISO 7405:2008 - Dentistry -- Evaluation of biocompatibility of medical devices used in dentistry
- EN 1641:2009 - Dentistry. Medical devices for dentistry. Materials
- ISO 10993-1:2009 – 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: Tests for in vitro cytotoxicity
- ISO 10993-18:2005 - Biological evaluation of medical devices -- Part 18: Chemical characterization of materials

The device passed all testing and is determined to be substantially equivalent to the unmodified Ceramill® ZI device.

10. Clinical Performance Data

There was no human clinical testing required to support the medical device as the intended use is the same as the predicate device. These types of devices, including the predicate devices, have been used successfully for many years. 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, but can be demonstrated to be substantially equivalent to the predicate device, and does not raise additional questions regarding its safety and effectiveness.

As such, the nonclinical tests conducted that demonstrate that the Ceramill® Zolid HT+ white device is as safe and effective as the unmodified Ceramill® ZI, and is determined to be substantially equivalent to predicate device.