December 20, 2019

Amann Girrbach AG
% Rachel Paul
Senior Consultant QA & RA
Emergo Europe Consulting
Prinsessegracht 20
The Hague, 2514AP Nl

Re: K191836
Trade/Device Name: Ceramill A-Splint
Regulatory Class: Unclassified
Product Code: MQC
Dated: October 28, 2019
Received: October 31, 2019

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191836

Device Name

Ceramill A-Splint

Indications for Use *(Describe)*

Ceramill A-Splint is indicated for the fabrication of removable bite splints.

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) K191836 Summary

Ceramill A-Splint

1. **Submission Sponsor**

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3. **Date Prepared**

28 October 2019

4. **Device Identification**

Trade/Proprietary Name: Ceramill A-Splint

Common/Usual Name: Occlusal splints

Classification Name: Mouthguard, Prescription

Regulation Number: N/A - Unclassified

Product Code: MQC

Device Class: N/A - Unclassified

Classification Panel: Dental

5. Legally Marketed Predicate Device

K134015, M-PM-Disc (Clear), Merz Dental GmbH

6. Indication for Use Statement

Ceramill A-Splint is indicated for the fabrication of removable bite splints.

7. Device Description

Ceramill A-Splint are ready to use, polymethyl methacrylate (PMMA) based computer-aided design/computer-aided manufacturing (CAD-CAM) blanks, for milling splints. Ceramill A-Splint is available as a disk (round form) or as an arch-form (or "U"-shape).

8. Comparison of Technology

The following table compares the Ceramill A-Splint to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. There are no differences in technology.

Table 5A – Comparison of Technology

Attribute	**Ceramill A-Splint**	**M-PM-Disc**	**Comparison**
Manufacturer	Amann Girrbach AG	Merz Dental GmbH	N/A
510(k) Number	To be determined (TBD)	K134015	N/A
Product Code	MQC	MQC	Same
Regulation Reference	Unclassified	Unclassified	Same
Indications for Use	Ceramill A-Splint is indicated for the	The Merz Dental GmbH M-PM-Disc (Clear) is indicated for the	Similar; both devices are indicated for the production of removable

Attribute	Ceramill A-Splint	M-PM-Disc	Comparison
	fabrication of removable bite splints.	fabrication of removable bite splints such as mouthguards and nightguards.	bite splints. The indications for use of Ceramill A-Splint fall within the intended use of unclassified mouthguard devices. Both devices are for prescription only.
Material	Solid Polymethylmethacrylate (PMMA) No pigments	Solid Polymethylmethacrylate (PMMA) No pigments	Same
Residual monomer	Less than 1% residual monomer	Less than 1% residual monomer	Same; both devices meet requirements from ISO 20795-2:2013 (<5).
Shape, sizes	Available in round and arch shapes respectively of 98 and 71 mm with three (3) different height (14, 16, 20 mm).	Available only in round shape from 90 x 15 to 114.8 x 25 mm.	Similar; the arch shape does not introduce any additional safety or efficacy concerns. Dimensions are in the same range.
3-point bending strength	>100 MPa	91.5 MPa - 96.6 MPa	Similar; the specifications are in the same range. This minor variance does not introduce additional safety or efficacy concerns. Both devices meet requirements from ISO 20795-2:2013[1] (≥50).
Water solubility	<0.7 µg/mm^3	0.2 µg/mm^3	Similar; the specifications are in the same range. This minor variance does not introduce additional safety or efficacy concerns.

[1] ISO 20795-2 :2013 Dentistry – Base polymers : Part 2 : Orthodontic base polymers (FDA Recognition Number: 4-233).

Attribute	Ceramill A-Splint	M-PM-Disc	Comparison
			Both devices meet requirements from ISO 20795-2:2013 (≤5).
Water absorption	<25 µg/mm^3	26.5 µg/mm^3	Similar; the specifications are in the same range. This minor variance does not introduce additional safety or efficacy concerns. Both devices meet requirements from ISO 20795-2:2013 (≤32).
Flexural modulus	≥ 2000 MPa	Unknown	The submission device meet requirements from ISO 20795-2:2013 (≥ 1500).
Fracture toughness (maximum stress intensity (K_{max}) and total fracture work (W_f))	K_{max}≥ 1.1 MPa m$^{1/2}$ Wf ≥ 250 J/m^2	Unknown	The submission device meet requirements from ISO 20795-2:2013 (K_{max} ≥ 1.1 and W_f ≥ 250).
Sterile	Delivered and use non-sterile	Delivered and use non-sterile	Same
Single-Use	Yes	Yes	Same
Complies with ISO 10993-1	Yes	Yes	Same

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of Ceramill A-Splint and to show substantial equivalence to the predicate device, Amann Girrbach AG completed the following non-clinical tests.

The Ceramill A-Splint passed the testing in accordance with internal requirements, national standards, and international standards shown below:

- Biocompatibility assessment was conducted according to ISO 10993-1. Considering the chemically defined composition, the existing dental history with PMMA polymers and the inert material properties substantiated by highly sensitive chemical analysis, it was determined that no other

biocompatibility testing than cytotoxicity testing was required. No cytotoxic effects were observed in presence of the test material extracts.

- Bench performance testing conducted in conformity with ISO 20795-2:2013 met all of the requirements set forth in the standard for residual monomer testing, 3-point bending strength, water solubility, water absorption, flexural modulus, fracture toughness, polishability, and porosity.
- Wearing testing based on an adapted Ivoclar method in a chewing simulator – the wearing period has been determined to be of a maximum of three years.
- Shelf Life Testing – it was demonstrated that key characteristics do not degrade after four years of storage.

10. Conclusion

Based on similarities in intended use, indications for use statements, technology, and non-clinical performance testing, Amann Girrbach believes that Ceramill A-Splint is substantially equivalent to the predicate device (K134015).