June 29, 2026

Amann Girrbach AG
℅ Oliver Eikenberg
Global QA/RA Manager
Pure Global
111 Town Sq. Pl.
Suite 1203
Jersey City, New Jersey 07310

Re: K260918
Trade/Device Name: Zolid Lunaris
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: March 19, 2026
Received: March 19, 2026

Dear Oliver Eikenberg:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260918

Device Name
Zolid Lunaris

Indications for Use *(Describe)*
Zolid Lunaris is a zirconia ceramic CAD/CAM blank (type II, class 5 according to ISO 6872) for manufacturing fixed dental prostheses to restore tooth anatomy, physiology and aesthetics in (partially) edentulous patients.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary (traditional)

Zolid Lunaris

K260918

Date Prepared: 26 June 2026

510(k) Owner / Applicant Submission Sponsor

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Submission Correspondent

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Device Information

Trade Name: Zolid Lunaris

Common Name: Powder, Porcelain

Regulation Number: 21 CFR 872.6660

Regulation Name: Porcelain powder for clinical use

Product Code: EIH

Classification: Class II

Review Panel: Dental

Legally Marketed Predicate Device

Primary Predicate Device Name Ceramill® Zolid HT+ white

510(k) Number: K171876

Manufacturer: Amann Girrbach AG

Regulation Number: 21 CFR 872.6660

Regulation Name: Porcelain powder for clinical use

Product Code: EIH

Classification: Class II

Review Panel: Dental

Device Description

Zolid Lunaris is a zirconia ceramic CAD/CAM blank (type II, class 5 according to ISO 6872) for manufacturing fixed dental prostheses to restore tooth anatomy, physiology and aesthetics in (partially) edentulous patients. The fixed dental prosthesis is intended for single use.

The indications are for Replacement of missing or damaged teeth by means of

- Single tooth dental restorations
- Multi-unit dental restorations

Zolid Lunaris disc-shaped blanks are available in 7 different sizes (Ø x height in mm): 98 x 12, 98 x 14, 98 x 16, 98 x 18, 98 x 20, 98 x 25, 98 x 30.

The zirconia ceramic CAD/CAM blank is supplied non-sterile.

The device achieves its intended medical purpose through its mechanical and material properties – namely high flexural strength (≥800 MPa) and fracture toughness (≥4.0MPa√m) according to ISO 6872 – allowing for long-term intraoral use. Due to its mechanical properties (Y-TZP ZrO_2), Zolid Lunaris is classified as Type II, Class 5 ceramic according to ISO 6872.

Once the dental restoration is fabricated and placed in the patient`s mouth, it functions to restore the tooth anatomy, function, and aesthetics in patients with missing or damaged teeth while integrating harmoniously with the surrounding tissues. The 3Y-TZP basal zone provides mechanical stability, while the 4Y-TZP incisal zone enhances optical properties, offering an optimized balance between strength and aesthetics.

Substantial Equivalence Discussion –

FEATURE	**SUBJECT DEVICE**	**PREDICATE DEVICE**	**COMPARISON / COMMENT**
Manufacturer	**Amann Girrbach AG**	**Amann Girrbach AG**	
Trade Name	**Zolid Lunaris**	**Ceramill® Zolid HT+ white**	
INTENDED USE COMPARISON			
510(k) Number	K260918	K171876	N/A
Product Code	EIH	EIH	same
Regulation Number	21 CFR 872.6660	21 CFR 872.6660	same
Regulation Name	Porcelain powder for clinical use	Porcelain powder for clinical use	same
Indications for Use	Zolid Lunaris is a zirconia ceramic CAD/CAM blank (type II, class 5 according to ISO 6872) for manufacturing fixed dental prostheses to restore tooth anatomy, physiology and aesthetics in (partially) edentulous patients.	Zirconium-oxide blanks for permanent and removable dental prosthetics.	same

FEATURE	SUBJECT DEVICE	PREDICATE DEVICE	COMPARISON / COMMENT
Manufacturer	**Amann Girrbach AG**	**Amann Girrbach AG**	
Trade Name	**Zolid Lunaris**	**Ceramill® Zolid HT+ white**	
Conditions of Use	Replacement of missing or damaged teeth by means of -Single tooth dental restorations -Multi-unit dental restorations	-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 further than the second premolar).	same
Contraindications	-Insufficient tooth structure -Known allergies and intolerances to the material in the medical device -Periapical inflammation or existing periodontal disease -Insufficient root fillings -All indications that are not listed under “Indications”	-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
Intended User	Professionally trained dental technicians and dentists.	The product may only be used by trained dental technicians.	same
Prescription Use	Yes	Yes	same
TECHNICOLOGICAL CHARACTERISTIC COMPARISON			

FEATURE	SUBJECT DEVICE	PREDICATE DEVICE	COMPARISON / COMMENT
Manufacturer	**Amann Girrbach AG**	**Amann Girrbach AG**	
Trade Name	**Zolid Lunaris**	**Ceramill® Zolid HT+ white**	
Physical Form / State	Solid	Solid	same
Chemical Composition	$ZrO_2 + HfO_2 + Y_2O_3 \geq 99.0$ wt. % Y_2O_3: 6.3 – 7.2 wt. % HfO_2: ≤ 5.0 wt. % Al_2O_3: ≤ 0.01 wt. % Others oxides: ≤ 1.0 wt. %	$ZrO_2 + HfO_2 + Y_2O_3 \geq 99.0$ wt. % Y_2O_3: 6.7 – 7.2 wt. % HfO_2: ≤ 5.0 wt. % Al_2O_3: ≤ 0.5 wt. % Others oxides: ≤ 1 wt. %	similar
Shapes	Disks (round-shape)	Disks (« U »-shape or round-shape)	similar
Dimensions	98 mm of diameter, in seven different heights (12, 14, 16, 18, 20, 25, 30 mm).	"U"-shape: 90 x 72, in eight different heights (10, 12, 14, 16, 18, 20, 25, 30 mm). - Round-shape: 98 mm of diameter, in eight different heights (10, 12, 14, 16, 18, 20, 25, 30 mm).	similar
Shades	16 VITA shades (A1 - D4) and four bleach shades (BL0, BL1, BL2, BL3)	white	different
Supplied sterile	Non-sterile.	Non-sterile.	same
Sintering Temperature and Duration	1500 °C – 2 hours	1450 °C – 2 hours	similar - Both meet ISO 6872:2024
Shelf life	4 years	5 years	similar
Flexural Strength	≥800 MPa acc. to ISO 6872	1100 ± 150 MPa acc. to ISO 6872	similar - Both meet ISO 6872:2024 minimum average strength of 800 MPa thus, both are classified as dental ceramics of Type II, Class 5.
E-module	≥200 GPa	≥ 200 GPa	same
Thermal expansion coefficient (CTE) (25-500°C)	10.5±0.5 (10^{-6}/K)	10.4 ± 0.5 (10^{-6}/K)	similar
Chemical Solubility	<100 µg/cm² acc. to ISO 6872	<100 µg/cm² acc. to ISO 6872	same
Vickers hardness	1300±200 HV10	1300 ± 200 HV10	same
Final Density	≥ 6.05 g/cm^3	≥ 6.05 g/cm^3	same
Porosity (%)	0 (no open porosity)	0 (no open porosity)	same
Grain Size	≤ 0.7 µm	≤ 0.6 µm	similar
Radioactivity	≤ 1.0 Bq/g	≤ 1.0 Bq/g	same
Biocompatibility	Verified by cytotoxicity testing according to ISO 10993-5 and chemical analysis for organic and inorganic extractables according to ISO 10993-18.	Verified by cytotoxicity testing according to ISO 10993-5 and chemical analysis for organic and inorganic extractables according to ISO 10993-18.	same

Any minor differences do not raise new questions regarding safety or effectiveness.

The following testing and evaluations demonstrate that the subject device performs safely and effectively:

- **Performance Testing acc. to ISO 6872**: Meets the ISO 6872 standard for type II, class 5 zirconia ceramics (flexural strength ≥800 MPa, chemical solubility <100 µg/cm²).
- **Biocompatibility acc. to ISO 10993**: Passed ISO 10993 tests with no cytotoxic effects, confirming its safety for use in dental applications.
- **Packaging**: Validated to ensure packaging stability, protecting the product during storage and transit for the defined shelf life.
- **Stability and Shelf-Life**: 4 years, with no degradation or adverse effects expected.
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Conclusion

Based on the comparison of intended use, technological characteristics, and performance data, the subject device **Zolid Lunaris** is substantially equivalent to the predicate device **Ceramill® Zolid HT+ white (K171876).** Differences in chemical composition, shapes, dimensions, shades, sintering temperature and duration, shelf life, flexural strength, thermal expansion coefficient (CTE) and grain size do not raise new questions of safety or effectiveness.