June 11, 2026

HASS Corp.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
2552 Walnut Ave.
Suite 230
Tustin, CA 92780 USA

Re: K260859
Trade/Device Name: Rosetta SM, Rosetta SP
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: March 16, 2026
Received: March 16, 2026

Dear Priscilla Chung:

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260859

Device Name

Rosetta SM, Rosetta SP

Indications for Use *(Describe)*

Rosetta SM is CAD/CAM machinable glass ceramic based on lithium disilicate for the preparation of full ceramic crowns, inlays, onlays, and full ceramic 3-unit anterior bridges.

Rosetta SP is an all-ceramic system for the creation of occlusal veneers, thin veneers, veneers, inlays, onlays, crowns in the anterior and posterior region, 3-unit bridges in the anterior region, 3-unit bridges in the premolar region up to the second premolar as the terminal abutment, and crown, splinted crown or 3-unit bridge up to the second premolar placed on top of an implant abutment.

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.

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510(k) Summary

(K260859)

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: ___June 10, 2026___

1. Applicant / Submitter:

HASS Corp.
77-14, Gwahakdanji-ro
Gangneung-si Gangwon, South Korea, 25452
Tel: 82- 70-7712-1300

2. Submission Correspondent:

Priscilla Chung
LK Consulting Group USA, Inc.
2552 Walnut Ave Ste 230, Tustin CA 92780
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device:

Proprietary Name:	Rosetta SM, Rosetta SP
Common Name:	Dental Frame Material for Dental Prosthesis
Classification Name:	Porcelain Powder for Clinical Use (21 CFR 872.6660, Product Code: EIH)

4. Predicate Device:

- Primary Predicate Device: IPS E.MAX CAD/IPS E.MAX ZIRCAD (K051705) by Ivoclar VIVAdent Co,. Ltd.
- Reference Device: IPS e.max Press/IPS emax Press Multi (K120134) by Ivoclar VIVAdent Co,. Ltd.

5. Device Description:

Rosetta SM Series and Rosetta SP Series are a Glass Ceramic to be supplied in the form of Blocks and Ingots. Rosetta SM can be fabricated using CAD/CAM technologies. The subject devices are intended to be milled to produce prosthetic restorations for natural and endosseous dental implant abutment borne teeth. The subject devices are glass type material used for aesthetic purposes of single front-teeth, veneer, inlay, onlay and crown.

Rosetta SP is an all-ceramic system for the creation of occlusal veneers, thin veneers, veneers, inlays, onlays, crowns in the anterior and posterior region, 3-unit bridges in the anterior region, 3-unit bridges in the premolar region up to the second premolar as the terminal abutment, and crown, splinted crown or 3-unit bridge up to the second premolar placed on top of an implant abutment.

The ceramics material is composed of SiO2, Li2O, P2O5, Al2O3 and other oxides. It also contains inorganic pigments to provide different shades on the product surface. Rosetta SM offers 36 different size/shape series and each series offers 48 different shades. Rosetta SP offers 4 different size series, and each series offers 48 different shades. Each different sizes is to be used with various equipment for CAD/CAM milling and to meet the needs of patients' various tooth shapes. 48 different shades are offered to meet the needs of different patient's tooth colors. The subject devices don't need sintering since they are provided fully crystallized.

The difference between Rosetta SM and Rosetta SP is the manufacturing process, which is divided into Rosetta SM, which is a block type of milling type, and Rosetta SP, which is an ingot type of pressing type. The raw materials, indications, etc. are the same between the two.

6. Indications for Use:

Rosetta SM is CAD/CAM machinable glass ceramic based on lithium disilicate for the preparation of full ceramic crowns, inlays, onlays, and full ceramic 3-unit anterior bridges.

Rosetta SP is an all-ceramic system for the creation of occlusal veneers, thin veneers, veneers, inlays, onlays, crowns in the anterior and posterior region, 3-unit bridges in the anterior region, 3-unit bridges in the premolar region up to the second premolar as the terminal abutment, and crown, splinted crown or 3-unit bridge up to the second premolar placed on top of an implant abutment.

7. Performance Data (Non-Clinical):

The following tests were performed on the subject device and the test results support that the subject device is substantially equivalent to the predicate devices.

- Performance Tests: Visual, Dimension, Weight, Packaging, Uniformity (ISO 6872), Free from Extraneous Materials (ISO 6872), Radioactivity (ISO 6872), Chemical Solubility (ISO 6872), Flexural Strength (Three-point bending) (ISO 6872), Flexural Strength (Biaxial flexture) (ISO 6872), Linear Thermal Expansion Coefficient (ISO 6872), Glass Transition Temperature (ISO 6872), Fracture Toughness (ISO 6872)

- Biocompatibility Tests: Cytotoxicity (ISO 10993-5), Acute Systemic Toxicity (ISO 10993-11), Oral Mucosa Irritation (ISO 10993-10), Skin Sensitization (ISO 10993-10)

8. Substantial Equivalence

8.1. Comparison Chart

	Proposed Device	Predicate Device	Reference Device	Comparison Discussion
510(k) Number	K260859	K051705	K120134	
Device Name	Rosetta SM Rosetta SP	IPS E.MAX CAD/IPS E.MAX ZIRCAD	IPS e.max Press/IPS emax Press Multi	-
Common Name	Porcelain powder for clinical use	Porcelain powder for clinical use	Porcelain powder for clinical use	Same
Manufacturer	HASS CORPORATION.	Ivoclar VIVAdent Co,. Ltd.	Ivoclar VIVAdent Co,. Ltd.	-
Indication For Use	Rosetta SM is CAD/CAM machinable glass ceramic based on lithium disilicate for the preparation of full ceramic crowns, inlays, onlays, and full ceramic 3-unit anterior bridges. Rosetta SP is an all-ceramic system for the creation of occlusal veneers, thin veneers, veneers, inlays, onlays, crowns in the anterior and posterior region, 3-unit bridges in the anterior region, 3-unit bridges in the premolar region up to the second premolar as the terminal abutment, and crown, splinted crown or 3-unit bridge up to the second premolar placed on top of an implant abutment.	IPS e.max CAD is a CAD/CAM machinable glass ceramic based on lithium disilicate for the preparation of full ceramic crowns, inlays, onlays, and full ceramic 3-unit anterior bridges. IPS e.max ZirCAD consists of machinable zirconia blocks for the preparation of full ceramic crowns, onlays and 3- and 4-unit bridges and inlay bridges (anterior and molar.)	IPS e.max Press and IPS emax Press Multi is an all-ceramic system for the creation of occlusal veneers, thin veneers, veneers, inlays, onlays, crowns in the anterior and posterior region, 3-unit bridges in the anterior region, 3-unit bridges in the premolar region up to the second premolar as the terminal abutment, and crown, splinted crown or 3-unit bridge up to the second premolar placed on top of an implant abutment.	Same
Classification Reg	21 CFR 872.6660	21 CFR 872.6660	21 CFR 872.6660	Same

FDA Product Code	EIH	EIH	EIH	Same
Materials	SiO_2, Li_2O, ZrO_2	SiO_2, Li_2O, ZrO_2	SiO_2, Li_2O, ZrO_2	Same
Crystallization State as Supplied	Fully crystallized	Fully crystallized	Fully crystallized	Same
Size	Rosetta SP : R10, R15, R20 Rosetta SM : C12, C14, C32, C40, Rosetta SM Disk : P98	C14, C16, I12 B32, B40	S, L	Similar
Shades	High, low and middle translucencies according to Vita shade guidance	High and low translucencies: 16 A-D and 4 Bleach BL shades	High translucencies: 16 A-D and 4 Bleach BL shades Middle translucencies: 9 A-D and 3 Bleach BL shades	Similar
Principle of Operation	A dental restoration or dental filling is a treatment to restore the function, integrity, and morphology of missing tooth structure resulting from caries or external trauma as well as to the replacement of such structure supported by dental implants.	A dental restoration or dental filling is a treatment to restore the function, integrity, and morphology of missing tooth structure resulting from caries or external trauma as well as to the replacement of such structure supported by dental implants.	A dental restoration or dental filling is a treatment to restore the function, integrity, and morphology of missing tooth structure resulting from caries or external trauma as well as to the replacement of such structure supported by dental implants.	Same
Type/Class per ISO 6872	Type 2 Class 3	Type 2 Class 3	Type 2 Class 3	Same
Flexural Strength	[Milling type: Rosetta SM] ・ Three-point bending: 332 MPa ・ Biaxial flexure: 307 MPa [Casting type: Rosetta SP] ・ Three-point bending: 333 MPa ・ Biaxial flexure: 310 MPa (meeting ISO 6872 requirements)	>300 MPa (meeting ISO 6872 requirements)	>300 MPa (meeting ISO 6872 requirements)	Similar
Chemical Solubility	[Milling type: Rosetta SM] 27.04 $\mu g/cm^2$	[Milling type: IPS e.max CAD] 10±5 $\mu g/cm^2$	[Casting type: IPS e.max Press] 40±10 $\mu g/cm^2$	Similar

	[Casting type: Rosetta SP] 30.10 ㎍/㎠ (meeting ISO 6872 requirements)	(meeting ISO 6872 requirements)	(meeting ISO 6872 requirements)	
Freedom from Extraneous Material	Dental ceramic was free from extraneous materials, when assessed by visual inspection (meeting ISO 6872 requirements)	Shall be free from extraneous materials when assessed by visual inspection (meeting ISO 6872 requirements)	Shall be free from extraneous materials when assessed by visual inspection (meeting ISO 6872 requirements)	Similar
Radioactivity	[Milling type: Rosetta SM] · 238U: 0.000124 Bq/g less, · 226Ra: 0.01 Bq/g less [Casting type: Rosetta SP] · 238U: 0.000124 Bq/g less, · 226Ra: 0.01 Bq/g less (meeting ISO 6872 requirements)	$_{238}$U less than 1.0Bq g-1 (meeting ISO 6872 requirements)	$_{238}$U less than 1.0Bq g-1 (meeting ISO 6872 requirements)	Similar
Coefficient of thermal expansion	10.1×10^{-6}/K °C (meeting ISO 6872 requirements)	10.5×10^{-6}/K °C (meeting ISO 6872 requirements)	10.5×10^{-6}/K °C (meeting ISO 6872 requirements	Similar
Glass Transition Temperature	[Milling type: Rosetta SM] 524 ℃ [Casting type: Rosetta SP] 539.80 ℃ (meeting ISO 6872 requirements)	560±10 ℃	560±10 ℃	Similar
Fracture Toughness ($MPa\cdot m^{1/2}$)	[Rosetta SM, Rosetta SP] 2.3 ± 0.2 $MPa\cdot m^{1/2}$ (meeting ISO 6872 requirements)	$2.0 – 2.5$ $MPa\cdot m^{1/2}$ (meeting ISO 6872 requirements)	$2.5 – 3.0$ $MPa\cdot m^{1/2}$ (meeting ISO 23146 requirements)	
Biocompatibility	Non-toxic and biocompatible (Meeting the ISO 10993-5, 10 and 10993-11 Requirements)	Non-toxic and biocompatible (Meeting the ISO 10993-5 Requirements)	Non-toxic and biocompatible (Meeting the ISO 10993-5 Requirements)	Same

8.2. Substantial Equivalence Discussion

The comparison carried out covers all products, models, sizes, and the entire intended purpose of the device under evaluation. The device under evaluation, which is the Glass ceramic block and ingot (model: Rosetta SM, Rosetta SP), is considerably similar to the equivalent devices in clinical, technical, and biological characteristics. Although there are some differences, they are not clinically significant difference in the performance and safety of the device. The differences are explained and not expected to significantly affect the clinical performance and clinical safety of the device under evaluation. In addition, all devices compared meet essential requirements, the data need to be in line with current knowledge/ the state of the art, be scientifically sound, cover all aspects of the intended purpose, and all products/ models/ sizes/ setting foreseen by the manufacturer without any undesirable side - effects according to identified literature and equivalent device information.

9. Conclusion:

Based on the testing results, HASS Corp. concludes that the Rosetta SM, Rosetta SP is substantially equivalent to the predicate devices.