August 26, 2021

HASS Corp.
% Priscilla Chung
Regulatory Affairs Consultant
Lk Consulting Group USA, Inc.
1150 Roosevelt STE 200
Irvine, California 92620

Re: K202952
Trade/Device Name: Amber Mill Q Series & Amber Mill Direct Series
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: May 19, 2021
Received: May 28, 2021

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 (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 Michael E. Adjodha, M.ChE.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202952

Device Name
Amber Mill Q Series & Amber Mill Direct Series

Indications for Use *(Describe)*
Once finalized into a suitable design, the Amber Mill Q Series and Amber Mill Direct Series are indicated for use as inlays, onlays, veneer, partial crowns and crowns.

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

(K202952)

This summary of 510(K) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 8/9/2021

1. Submitter

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2. U.S Agent/Contact Person

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3. Device

- Trade Name: Amber Mill Q Series & Amber Mill Direct Series
- Common Name: Dental Frame Material for Dental Prosthesis
- Classification Name: Porcelain Powder for Clinical Use
- Product Code: EIH
- Classification regulation: 21 CFR 872.6660

4. Primary Predicate Device:

Straumann n!ce Glass-Ceramic Blocks by Institut Straumann AG (K160262)

5. Description:

Amber Mill Q Series and Amber Mill Direct Series are a lithium disilicate ceramic to be supplied in the form of Blocks. Amber Mill Q Series & Amber Mill Direct Series 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 veneers, inlays, onlays, single-unit anterior and posterior crowns.
The ceramics material is composed of SiO2, Li2O, K2O, P2O5, Al2O3 and other oxides. It also contains inorganic pigments to provide different shades on the product surface. The subject device offers 18 different size/shape series and each series offers 45 different shades. 18 different sizes are to be used with various equipment for CAD/CAM milling and to meet the needs of patients' various tooth shapes. 45 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 only difference between Amber Mill Q Series and Amber Mill Direct Series is that the Amber Mill Q series has a hole in the center combined with a zirconia cap. The holes in Amber Mill Q are sizes compatible with abutment, through which are bonded to abutment to be connected to the implant.

The CAD/CAM systems and abutments compatible with Amber Mill Q series are as follows :

CAD/CAM System: Sirona Dental CAD/CAM system (K193408)
Abutment: Sirona TiBase (K193408)

6. Indication for use:

Once finalized into a suitable design, the Amber Mill Q Series and Amber Mill Direct Series are indicated for use as inlays, onlays, veneer, partial crowns and crowns.

7. Basis for Substantial Equivalence

Amber Mill Q Series and Amber Mill Direct Series are substantially equivalent to the Straumann n!ce Glass-Ceramic (K160262) The following comparison table is presented to demonstrate substantial equivalence.

	Proposed Device	**Primary Predicate Device**	**Comparison Discussion**
510(k) Number	K202952	K160262	Equivalent
Device Name	Amber Mill Q Series and Amber Mill Direct Series	Straumann n!ce Glass-Ceramic Blocks	-
Common Name	Porcelain powder for clinical use	Porcelain powder for clinical use	-
Manufacturer	HASS CORP.	Institut Straumann AG	-
Indication For Use	Once finalized into a suitable design, the Amber Mill Q Series and Amber Mill Direct Series are indicated for use as inlays, onlays, veneer, partial crowns and crowns.	Once finalized into a suitable design, the n!ce™ glass-ceramic blocks are indicated for use as inlays, onlays, veneer, partial crowns and crowns.	Equivalent
Classification Reg	21 CFR 872.6660	21 CFR 872.6660	Identical
FDA Product Code	EIH	EIH	Identical
Materials	SiO2, Li2O, K2O, P2O5, Al2O3 and other oxides	SiO2, Li2O, K2O, P2O5, Al2O3 and other oxides	Equivalent
Crystallization State as Supplied	Fully crystallized	Fully crystallized	Equivalent
Device Design	Block	Block	Equivalent
Size	C12 block(10 x 12 x 15mm) C14 block(12 x 14 x 18mm) C16 block(17.5 x 16 x 18mm)	C14 block(12.4 x14.5 x18.0mm)	(Similar)#1 * Proposed device and predicate device are essentially

			equivalent, but the proposed device has various size of models.
Shades	Various Translucency : High translucency(HT) Low translucency(LT) Medium Opacity(MO) Shade : LT/ HT : 16 A-D and 4 Bleach MO : 5 MO0- MO4	Various Translucency : High translucency(HT) Low translucency(LT) Shade : HT/ LT : 6 A-D	Equivalent
Principle of Operation	Fabricating restorations using CAD/CAM system	Fabricating restorations using CAD/CAM system	Equivalent
Type/Class per ISO 6872	Type Ⅱ, Class 3	Type Ⅱ, Class 2	(Similar)#2 * Proposed devices and predicate devices are essentially equivalent, but the indication vary depending on the classification of clinical use in ISO 6872. Classification is determined by mechanical and chemical properties. The result of flexural strength tested according to ISO 6872 standard is 519 MPa, so it corresponds to Class 3 according to Table 1. Classification table.
Flexural strength	> 300MPa (meeting the ISO6872 requirements)	> 100MPa (meeting the ISO6872 requirements)	Equivalent
Chemical solubility	< 100 ug / cm^2 (meeting the ISO6872 requirements)	< 100 ug / cm^2 (meeting the ISO6872 requirements)	Equivalent
Freedom from Extraneous Material	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)	Equivalent
Radioactivity	Activity concentration of $uranium^{238}$ less than 1.0Bq g^{-1} (meeting the ISO6872 requirements)	Activity concentration of $uranium^{238}$ less than 1.0Bq g^{-1} (meeting the ISO6872 requirements)	Identical
Linear of thermal expansion	11.5±0.5 × 10^{-6}/℃ (meeting the ISO6872 requirements)	12.0±0.5 × 10^{-6}/℃ (meeting the ISO6872 requirements)	Equivalent
Glass Transition Temperature	Activity concentration of $uranium^{238}$ less	Activity concentration of $uranium^{238}$ less	Equivalent

	than 1.0Bq g-1 (meeting ISO 6872 requirements)	than 1.0Bq g-1 (meeting ISO 6872 requirements	
Biocompatibility	Non-toxic and biocompatible (Meeting the ISO 10993-3, 5, 10 and 10993-11 Requirements)	Non-toxic and biocompatible (Meeting the ISO 10993-5 and 10993-10 Requirements)	Equivalent

Substantial Equivalence Discussion

The subject device has the same intended use and the same principle of operation as the predicate devices. The subject device and the predicate devices might have a slight difference in compositions but all the devices
have SiO_2, Li_2O, K_2O, P_2O_5, and Al_2O_3 as major components.
Despite this difference, the test results per ISO 6872 shows that the subject device is substantially equivalent to the predicate device in physical and chemical properties and meets the necessary requirements.
In addition, the subject device has been tested for Cytotoxicity (ISO 10993-5), Sensitization (ISO 10993-10), and Irritation (ISO 10993-10) to meet the biocompatibility requirements.
Based on the test results and the information provided in this submission, we conclude that the subject device is substantially equipment to the predicate devices.

8. Non-Clinical Testing

- Performance Tests including Flexural strength, Chemical solubility, Freedom from Extraneous Material, Radioactivity, Linear of thermal expansion, Glass Transition Temperature in accordance with ISO 6872
- Biocompatibility tests in accordance with ISO 10993-5, 10, and 11.

9. Conclusion

The subject device and the predicate device have the same intended use and have the same technological characteristics. Based on the similarities and the test results, we conclude that the subject device is substantially equivalent to the predicate device.