DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 14, 2016

Hass Corp.
Ms. Priscilla Chung
Regulatory Affairs Consultant
Lk Consulting Group Usa, Inc.
2651 E Chapman Ave Ste 110
Fullerton, California 92831

Re: K160102
Trade/Device Name: Amber Mill Series And Amber Press Series
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: January 12, 2016
Received: January 19, 2016

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. 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 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 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 yours,

Michael J. Ryan -S

for Erin I. Keith, M.S.
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)*
K160102

Device Name

Amber Mill Series and Amber Press Series

Indications for Use *(Describe)*

Amber Mill Series are indicated for fabricating glass ceramic restorations such as single-unit anterior and posterior crowns, veneers, inlays/onlays, and anterior 3-unit bridges using CAD/CAM System.
Amber Press Series are indicated for fabricating glass ceramic restorations such as single-unit anterior and posterior crowns, veneers, inlays/onlays, and anterior 3-unit bridges using hot press technique.

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

(K160102)

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

Date: July 12, 2016

1. Applicant / Submitter:

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2. Submission Correspondent:

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3. Device:

Proprietary Name:	Amber Mill Series and Amber Press Series
Common Name:	Dental Frame Material for Dental Prosthesis
Classification Name:	Porcelain Powder for Clinical Use
Classification:	Class II, 21 CFR 872.6660
Classification Product Code:	EIH

4. Predicate Device:

Obsidian™ Milling Blocks by Prismatik Dentalcraft, Inc. (K141788)
Obsidian™ Press(All-Ceramic and POM) by Prismatik Dentalcraft, Inc. (K141887)

5. Device Description:

Amber Mill Series and Amber Press Series are a lithium silicate ceramic to be supplied in the form of Ingots & Blocks. Amber Mill can be fabricated using CAD/CAM technologies and Amber Press can be fabricated using hot press technique.
This dental material is glass type material used for aesthetic purposes of veneers, inlay/onlay, partial crowns, anterior crowns, 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 31 different size/shape series and each series offers 45 different shades. 31 different sizes are to be used with various equipments for CAD/CAM milling or hot press and to meet the needs of patients' various tooth shapes. 45 different shades are offered to meet the needs of different patients tooth colors.

6. Principles of Operation:

Amber Mill Series and Amber Press Series are glass type dental material which can be fabricated using CAD/CAM technologies or hot press technique to make restorations such as single-unit anterior and posterior crowns, veneers, inlays/onlays, and anterior 3-unit bridges not involving molar restoration. These blanks correspond to ISO 6872, Dentistry: Ceramic Materials.
The subject devices offer various sizes and shades to meet the needs of different patients' tooth shapes and colors.

7. Technological Characteristics Summary:

Material	Glass Ceramic
Category	Dental Frame Material for Dental Prosthesis
Color	Various (High , Low translucencies and Medium Opacity): 16 A-D and 4 Bleach W shades
Odor	Odorless
Flexural strength	> 300MPa
Chemical solubility	< 100 ug / cm^2
Glass Transition Temperature (Tg)	553 ℃

8. Intended Use:

Amber Mill Series are indicated for fabricating glass ceramic restorations such as single-unit anterior and posterior crowns, veneers, inlays/onlays, and anterior 3-unit bridges using CAD/CAM System.
Amber Press Series are indicated for fabricating glass ceramic restorations such as single-unit anterior and posterior crowns, veneers, inlays/onlays, and anterior 3-unit bridges using hot press technique.

9. Performance Data(Non-Clinical):

The following properties were tested based on the referenced standards. All the test results support substantial equivalence to the predicate devices.

- ISO 6872 – Uniformity, Foreign Body, Chemical Solubility, Flexural Strength, Radioactivity, Linear Thermal Expansion, Glass Transition Temperature tests
- ISO 10993-3 - Genotoxicity
- ISO 10993-5 – Cytotoxicity
- ISO 10993-10 - Sensitization & Irritation
- ISO 10993-11 – Systemic Toxicity(oral)
- Other bench testing – Visual Inspection, Size, Package tests

Test Title	Test Standard	Requirement/Criteria	Test Result
Visual Inspection Report	-	There shall be no extraneous materials, distributing at use when assessed by visual inspection.	There were no extraneous materials, distributing at use when assessed by visual inspection.
Size Test Report	-	The size tolerance should be within +/- 2mm	PASS
Package Test Report	-	There shall be no breakage, no crack, no pollution of foreign body and no problem of use in product.	There was no breakage, no crack, no pollution of foreign body and no problem of use in product.
Uniformity Test Report	ISO 6872	Colorants shall be dispersed uniformly on the block.	Colorants were dispersed uniformly on the block.
Foreign Body Test Report	ISO 6872	It shall be free from extraneous materials.	They were free from extraneous materials.
Chemical Solubility Test Report	ISO 6872	less than 100 $\mu g/cm^2$	PASS
Flexural Strength Test Report	ISO 6872	Over 300 MPa	PASS
Radioactivity Test Report	ISO 6872	U^{238}: Less than 1.0 Bq/g	PASS
Linear Thermal Expansion Test Report	ISO 6872	$10.0 +/- 0.5\ 10^{-6}K^{-1}$	PASS

Glass Transition Temperature Test Report	ISO 6872	550+/- 20 °C	PASS
Genotoxicity	ISO 10993-3	< 2.0	PASS
Cytotoxicity test	ISO 10993-5	≥ 70%	PASS
Irritation test	ISO 10993-10	No mutation	PASS
Sensitization test	ISO 10993-10	< 1.6	PASS
Systemic toxicity(oral) test	ISO 10993-11	No abnormality and death	PASS

10. Substantial Equivalence

Amber Mill Series and Amber Press Series are substantially equivalent to the Obsidian™ Milling Blocks (K141788) and Obsidian™ Press (K141887). Two predicate devices are chosen for showing substantial equivalence to the predicate devices in the market in terms of milling methods employed for the materials which are CAD/CAM and pressing methods.

The following comparison table is presented to demonstrate substantial equivalence.

	Proposed Device	**Primary Predicate Device**	**Reference Predicate Device**	**Substantial Equivalence**
510(k) Number	K160102	K141788	K141887	-
Manufacturer	HASS CORP.	Prismatik Dentalcraft, Inc.	Prismatik Dentalcraft, Inc.	-
Device Name	Amber Mill Series Amber Press Series	Obsidian™ Milling Blocks	Obsidian™ Press(All-Ceramic and POM)	-
Common Name	Porcelain powder for clinical use	Porcelain powder for clinical use	Porcelain powder for clinical use	Same
CFR Section	21 CFR 872.6660	21 CFR 872.6660	21 CFR 872.6660	Same
Product Code	EIH	EIH	EIH	Same
Type and class according to ISO 6872	Monolithic Ceramic Class 3	Monolithic Ceramic Class 3	Monolithic Ceramic Class 3	Same

Indication For Use	Amber Mill Series are indicated for fabricating glass ceramic restorations such as single-unit anterior and posterior crowns, veneers, inlays/onlays, and anterior 3-unit bridges using CAD/CAM System. Amber Press Series are indicated for fabricating glass ceramic restorations such as single-unit anterior and posterior crowns, veneers, inlays/onlays, and anterior 3-unit bridges using hot press technique.	The Obsidian™ Milling Blocks is used to fabricate ceramic dental prostheses in the nature of crowns and bridges for posterior and anterior applications using CAD/CAM methods.	The Obsidian™ Press ceramic is used to fabricate Press Over Metal dental prostheses in the nature of crowns and bridges as well as monolithic dental prostheses in the nature of crowns, partial crowns, veneers, inlays, and onlays for posterior and anterior applications, as well as 3-unit anterior bridges (including pre-molar region as terminal abutment) using pressing methods.	Same
Materials	SiO2, Li2O, K2O, P2O5, Al2O3 and other oxides	SiO2, Li2O, K2O, P2O5, Al2O3 and other oxides	SiO2, Li2O, K2O, P2O5, Al2O3 and other oxides	Similar **The subject device and the predicate devices might have a slight difference in compositions but all the devices have SiO2, Li2O, K2O, P2O5, and Al2O3 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.
Main chemical compositions (in %)	Silicon dioxide(SiO_2) 71.45 ~ 78.07%	Silicon dioxide(SiO_2) (% not known)	Silicon dioxide(SiO_2) (% not known)	Similar
Summary of sizes and shapes	Form of Blocks : （12 × 5 × 15mm ~ 15.2 × 15.2 × 40mm) Form of Ingots : (Ø12.7×7mm ~Ø12.7×20mm)	Form of Blocks: （12 × 5 × 15 mm ~ 15.2 × 15.2 × 40mm)	Form of Ingots : (Ø12.7×7mm ~Ø12.7×20mm)	Similar
Shades	Various (High , Low translucencies and Medium Opacity): 16 A-D and 4 Bleach W	Various (A1, A2, A3, A3.5, B1, B2, B3, B4, C1, C2, C3, C4, BL1 and BL4)	Various (A1, A2, A3, A3.5, B1, B2, B3, B4, C1, C2, C3, C4, BL1and BL4)	Similar **The subject device and the predicate devices might have a slight

	shades			difference in shades. Despite this difference, the test results per ISO 6872 and 10993 standards show that the subject device is substantially equivalent to the predicate device in physical/chemical properties and biocompatibility, and meet the necessary requirements.
Principle of Operation	Fabricating restorations using hot press technique or CAD/CAM system	Fabricating restorations using CAD/CAM system	Fabricating restorations using hot press technique	Same
Performance tests performed	▪ ISO 6872 – Uniformity, Foreign Body, Chemical Solubility, Flexural Strength, Radioactivity, Linear Thermal Expansion, Glass Transition Temperature tests ▪ ISO 10993-3 - Genotoxicity ▪ ISO 10993-5 – Cytotoxicity ▪ ISO 10993-10 - Sensitization & Irritation ▪ ISO 10993-11 – Systemic Toxicity(oral) ▪ Other bench testing – Visual Inspection, Size, Package tests	▪ ISO 6872 – Foreign Body, Chemical Solubility, Flexural Strength, Radioactivity, Linear Thermal Expansion ▪ ISO 10993-5 – Cytotoxicity ▪ ISO 10993-10 - Sensitization & Irritation	▪ ISO 6872 – Foreign Body, Chemical Solubility, Flexural Strength, Radioactivity, Linear Thermal Expansion ▪ ISO 10993-5 – Cytotoxicity ▪ ISO 10993-10 - Sensitization & Irritation	Similar ** More performance tests were done on the subject devices.
Flexural strength	> 300MPa (meeting the ISO6872 requirements)	> 300MPa (meeting the ISO6872 requirements)	> 300MPa (meeting the ISO6872 requirements)	Similar **All devices meet ISO 6872 requirements.
Chemical solubility	< 100 ug / cm^2 (meeting the ISO6872 requirements)	< 100 ug / cm^2 (meeting the ISO6872 requirements)	< 100 ug / cm^2 (meeting the ISO6872 requirements)	Similar **All devices meet ISO 6872 requirements.
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)	Shall be free from extraneous materials when assessed by visual inspection (meeting ISO 6872 requirements)	Similar **All devices meet ISO 6872 requirements.
Radioactivity	Activity concentration of uranium^{238} less than 1.0Bq g^{-1}	Activity concentration of uranium^{238} less than 1.0Bq g^{-1}	Activity concentration of uranium^{238} less than 1.0Bq g^{-1}	Similar **All devices meet ISO 6872 requirements.

	(meeting the ISO6872 requirements)	(meeting the ISO6872 requirements)	(meeting the ISO6872 requirements)	
Linear of thermal expansion	$10.0\pm0.5 \times 10^{-6}$/℃ (meeting the ISO6872 requirements)	$12.0\pm0.5 \times 10^{-6}$/℃ (meeting the ISO6872 requirements)	$12.0\pm0.5 \times 10^{-6}$ / °C (meeting the ISO6872 requirements)	Similar **All devices meet ISO 6872 requirements.
Glass Transition Temperature	Activity concentration of uranium^{238} less than 1.0Bq g-1 (meeting ISO 6872 requirements)	Activity concentration of uranium^{238} less than 1.0Bq g-1 (meeting ISO 6872 requirements	Activity concentration of uranium^{238} less than 1.0Bq g-1 (meeting ISO 6872 requirements	Similar **All devices meet 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)	Non-toxic and biocompatible (Meeting the ISO 10993-5 and 10993-10 Requirements)	Similar **All devices meet ISO 10993 requirements.
Shelf-life	Semi-permanent	Semi-permanent	Semi-permanent	Same
Labeling	Package labeling and Instructions for Use	Package labeling and Instructions for Use	Package labeling and Instructions for Use	Same

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 SiO2, Li2O, K2O, P2O5, and Al2O3 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.

11. Conclusion:

Based on the testing results, HASS CORP. concludes that the Amber Mill Series and Amber Press Series are substantially equivalent to the predicate devices.