October 4, 2021

Aon Co., Ltd
Sanghwa Myung
Regulatory Affair Consultant
E&m
D-1474, 230, Simin-daero, Dongan-gu
Anyang, Gyeonggi-do 14067
SOUTH KOREA

Re: K211308
Trade/Device Name: Inni-cera
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: August 4, 2021
Received: August 6, 2021

Dear Sanghwa Myung:

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,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
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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)*

K211308

Device Name
INNI-CERA

Indications for Use *(Describe)*
INNI-CERA is indicated for use by dental technicians in the construction of custom made all ceramic restorations.

Coping
Crown
Inlay & Onlay
Veneer
Bridge(3-unit anterior bridges)

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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AON Co., Ltd

510(k) Summary

K211308

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Date 510(k) summary prepared: August 4th , 2021

Trade Name: INNI-CERA (BCM-W500, BCM-W1000)

Common Name: Dental Zirconia Material
Regulation Name: Porcelain Powder for Clinical Use
Classification: Class II
Product Code: EIH
Classification Panel: Dental
Regulation Numbers: 21 CFR 872.6660
Type of 510(k) submission: Traditional

Description of Device:

INNI-CERA is intended for use in fabricating custom-made ceramic restorations using a 3D printer additive manufacturing process. It is a product that is used after fabricating and sintering with a mixture of zirconia powder and binder. The DLP 3D printer used to fabricate the INNICERA is a photocuring lamination method using an STL file (dental restoration shape), which is irradiated with light in the strong UV region (420nm) to cure the photocurable mixture to form a model. This product corresponds to ISO 6872 Type I Class III. The material is used in a 3D printer, which prints the shape determined by an STL file converted from patients' teeth data. 3D printer is not included with the product. INNI-CERA cannot be reused.

Indication for use:

INNI-CERA is indicated for use by dental technicians in the construction of custom-made ceramic restorations.
Coping
Crown
Inlay & Onlay
Veneer
Bridge (3-unit anterior bridges)

Predicate Device:

Manufacturer: **Ivoclar Vivadent, Incorporated**

510(k) Number: K051705
Trade Name: IPS e.max ZirCAD
Regulation Name: Porcelain Powder for Clinical Use
Regulation Numbers: **21 CFR 872.6660**
Product Code: EIH
Classification: Class II

Substantial Equivalence:
Comparison table is as follows.

Table 1: Substantial equivalence comparison
1) Predicate Device

Contents	**Subject Device**	**Predicate Device**
Manufacturer	**Aon Co., Ltd**	**Ivoclar Vivadent, Incorporated**
510(k)Number	Pending	K051705
Trade Name	INNI-CERA	IPS e.max ZirCAD
Indication for Use	INNI-CERA is indicated for use by dental technicians in the construction of custom made all ceramic restorations. Crown Inlay & Onlay Veneer Bridge(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.)
Material	Zirconia	Zirconia
Material Type	Slurry	Block
Biocompatibility	According to EN ISO 10993-1	According to EN ISO 10993-1
Flexural Strength	>300 MPa (meeting ISO 6872 requirements)	>300 MPa (meeting ISO 6872 requirements)
Chemical Solubility	< 100μg/cm² (meeting ISO 6872 requirements)	< 100μg/cm² (meeting ISO 6872 requirements)
Radioactivity	Activity concentration of uranium238 less than 1.0Bq g-1	Activity concentration of uranium238 less than 1.0Bq g-1

	(meeting ISO 6872 requirements)	(meeting ISO 6872 requirements)
Sintering	YES	YES
Single Use	YES	YES
Non-sterile	YES	YES

- Discussion

The information provided in this subject device is equivalence of indication for use, material, biocompatibility, Flexural Strength, Chemical Solubility, Radioactivity with the predicate device (K051705). The minor difference is that INNI-CERA's material type is slurry and K051705 is a block type. It is a biocompatible material according to ISO 10993-1. Therefore, the difference in material types will not raise concern about safety and effectiveness.

2) Reference Device

Manufacturer: Enlighten Materials Co., Ltd
510(k) Number: K191590
Trade Name: AA temp temporary restoration 3D printing photoreactive resin
Regulation Name: Temporary crown and bridge resin
Regulation Numbers: 872.3770
Product Code: EBG
Classification: Class II

Contents	**Subject Device**	**Reference Device**	**Comparison Comment**
Manufacturer	**Aon Co., Ltd**	Enlighten Materials Co., Ltd	-
510(k)Number	Pending	K191590	-
Trade Name	INNI-CERA	AA temp temporary restoration 3D printing photoreactive resin	-
Indication for Use	INNI-CERA is indicated for use by dental technicians in the construction of custom made all ceramic restorations. Crown Inlay & Onlay Veneer Bridge(3-unit anterior bridges)	AA temp temporary restoration 3D printing photoreactive resin is a light-curable polymerizable resin to fabricate, by additive manufacturing, temporary crowns or bridges.	The manufacturing of restorations using a 3D printer is the same, the materials are different, but the use of dental materials for teeth is the same.
Biocompatibility	According to EN ISO 10993-1	According to EN ISO 10993-1	**Substantial Equivalent**
Production type	3D printing	3D printing	**Substantial Equivalent**
Non-sterile	YES	YES	**Substantial Equivalent**

Discussion

A reference device is a dental material manufactured by a 3d printer. K191590 is resin material but INNI-CERA is Zirconia material and It is a different material, but it is a biocompatible material according to ISO 10993-1. Both products manufacture dental restorations using 3D printer additive manufacturing. K191590 and subject device are used in a similar anatomical location for a similar physiological purpose. Therefore, the difference material will not raise concern of the safety and effectiveness.

Biocompatibility testing:

INNI-CERA dental zirconia materials were evaluated according to ISO 10993-1. The results of this test confirmed that it met the biocompatibility requirements. Biocompatibility testing, including cytotoxicity, sensitization, oral mucosal irritation, Acute Systemic Toxicity, Pyrogen Test, Subchronic systemic toxicity, Mammalian Erythrocyte Micronucleus Test (Carcinogenicity), AMES Test (Genotoxicity) was completed according to the following standards: ISO 10993-1 Biological Evaluation of Medical Devices –Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process ISO 10993-5 Biological Evaluation of Medical Devices – Part 5 Cytotoxicity ISO 10993-10 Biological Evaluation of Medical Devices Part 10: Tests for irritation and skin sensitization ISO 10993-12 Biological evaluation of medical devices-- ISO 10993-3: Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity, and reproductive and developmental toxicity, ISO 10993-11: Biological evaluation of medical devices —. Part 11: Tests for systemic.

Non-clinical Performance Data:

Bench Test:

In accordance with ISO 6872:2015 (Dentistry – Ceramic materials), the product must meet the requirements for flexural strength, chemical solubility, coefficient of thermal expansion, and radioactivity.

The Predicate device of IPS e.max ZirCAD (K051705) meets the requirements of the applicable class, as detailed in the table under Technological characteristics. The performance of INN-CERA meets the requirements of non-clinical bench testing was conducted to support substantial equivalence.

Shelf life testing, INNI-CERA has shelf life of 3 month. The shelf testing has been through accelerated aging test and confirm the performance accordance with ISO 6872:2015

Risk Management

A risk analysis was conducted based on ISO 14971:2012 Medical devices – Application of risk management to medical devices

. **Clinical Data:**

No clinical performance testing was performed.

Conclusion

In accordance with ISO 6872:2015 (Dentistry – Ceramic materials), the product must meet the requirements for flexural strength, chemical solubility, coefficient of thermal expansion, and radioactivity. The predicate IPS e.max ZirCAD(K051705) meet the requirements of the applicable Class, as detailed in Table under Technological Characteristics.
The performance of INN-CERA meets the requirements of the non-clinical bench testing conducted to support substantial equivalence. Based on the available information, the subject device and the predicates are similar indication for use, material, performance data and biocompatibility.
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification that we conclude that substantially equivalent with predicate device.