October 29, 2020

Hocheng Corporation
Chieh-Ju Huang
Manager
1F.,No.398, Xingshan Rd., Neihu Dist.
Taipei City, 11469 TAIWAN

Re: K193090
Trade/Device Name: HCG Zirconia Ceramic Block
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: July 29, 2020
Received: July 31, 2020

Dear Chieh-Ju Huang:

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 Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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)*
K193090

Device Name
HCG Zirconia Ceramic Block

Indications for Use *(Describe)*
HCG Zirconia Ceramic Block are intended for the fabrication and preparation of copings and full anatomical/full contour crowns, bridges, inlays, and onlays for anterior and posterior segment restorations.

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

1. Type of Submission: Traditional

2. Date of Summary: 10/26/2020

3. Submitter:

HOCHENG CORPORATION
Address: 1F.,No.398, Xingshan Rd., Neihu Dist., Taipei City 11469, Taiwan (R.O.C.)
Phone: +886-2-27925511
Fax: +886-2-27953101
Representative: CHIU-LI-CHIEN (cjhuang@hcgnet.com.tw)

4. Identification of the Device:

Proprietary/Trade name:	HCG Zirconia Ceramic Block
Classification Product Code:	EIH
Regulation Number:	872.6660
Regulation Description:	Porcelain powder for clinical use.
Review Panel:	Dental
Device Class:	II

5. Identification of the Predicate Device:

Predicate Device Name:	NexxZr™ S and NexxZr™ T
Manufacturer:	Sagemax Bioceramics, Inc.
Classification Product Code:	EIH
Regulation number:	872.6660
Device Class:	II
510(k) Number:	K130991

6. Identification of the Reference Device:

Reference Device Name:	Copran Zr/Origin YZ
Manufacturer:	White Peaks Dental System GmbH &

	Company KG
Classification Product Code:	EIH
Regulation number:	872.6660
Device Class:	II
510(k) Number:	K092496

7. Indications for Use / Intended Use of the Device

HCG Zirconia Ceramic Block are intended for the fabrication and preparation of copings and full anatomical/full contour crowns, bridges, inlays, and onlays for anterior and posterior segment restorations.

8. Description of the Device

"HCG Zirconia Ceramic Block" is a ceramic block composed of zirconia compounds. It is suitable for manufacture of dental crowns and bridges cut in the conventional manner or with the help of CAD/CAM.

9. Non-clinical Testing

A series of tests were conducted on the subject device, HCG Zirconia Ceramic Block.

Scope	Reference	Acceptance Criteria by Test Item	Test Result and SE
Shelf life	ASTM F1980	Visual inspection, Flexural strength, Chemical extraction, and Coefficient of linear expansion.	After aging, the test results met the pre-defined criteria according to the test standards. Thus the shelf life of the device is verified to demonstrate substantial equivalence.
	ISO 6872		
Biocompatibility	ISO 10993-5	*In Vitro* Cytotoxicity Test, Hemolysis Test, Acute Systemic Toxicity Study, Skin Sensitization	All the test results met the pre-defined criteria according to the test standards. Thus the
	ISO 10993-4		

	ISO 10993-11 ISO 10993-10 USP <151> ISO 10993-6	Study, White Rabbit Intracutaneous Reactivity Test, White Rabbit Pyrogen Test, Muscle Implant Study, and Repeated Dose 90-Day Subchronic Oral Toxicity Study in Rat	biocompatibility of the device is verified to demonstrate substantial equivalence.
Functional testing	ISO 6872 ISO 13356 CNS 13983 CNS 13958	Production quality of zirconia ceramic block, Size measurement of supporting shaft, and Efficacy of the subject, predicate and reference devices (basic physical and chemical characteristics)	All the test results met the pre-defined criteria according to the test standards, so the efficacy of the subject device is verified. The comparative testing of efficacy is also conducted on all devices, and the test results demonstrate substantial equivalence between subject, predicate and reference devices.

10. Clinical and Usability Testing

No clinical test data was used to support the decision of substantial equivalence.

11. Substantial Equivalence Determination

Equivalence, same and difference between the devices are cited as below.

Item	Subject device	Predicate device	Reference device	Substantial Equivalence Discussion
Trade Name	HCG Zirconia Ceramic Block	NexxZr™ S and NexxZr™ T	Copran Zr/Origin YZ	
510(k) No.	K193090	K130991	K092496	
Indication For Use /	HCG Zirconia Ceramic Block are	NexxZr™ are intended for the	Copran Zr/ Origin YZ Zirconia blanks are	***Equivalent*** All the devices are

Intended Use	intended for the fabrication and preparation of copings and full anatomical/full contour crowns, bridges, inlays, and onlays for anterior and posterior segment restorations.	fabrication and preparation of copings and full anatomical/full contour crowns, bridges, inlays, and onlays for anterior and posterior segment restorations.	presintered blanks for CAD CAM or manual milling, made from biocompatible, tetragonal and polycrystalline zirconiumdioxyde. Milling blanks designed for: - Crown friameworks in the anterior and posterior areas - Bridge frameworks in the anterior and posterior areas - Primary conical crowns and telescopic crowns - Cantilevered bridges with a max. of one pontic having a premolar width - Inlays, Onlays, Veneers	zirconia blocks and used for preparation of dental crowns, bridges, inlays, and onlays. Although the reference device has more specific usages on the crowns, bridges and veneers, the usage scope of subject device is smaller than that of reference device and the same as that of predicate device. Thus the differences between subject and reference devices does not raise new issues of SE.
Shape	round blocks (disks) and square blocks	disks	may be disks, cubes, bars, and cylinders.	***Equivalent*** Both subject device and reference device have the same shape.
Main component	ZrO_2; Y_2O_3; Al_2O_3	ZrO_2; Y_2O_3; HfO_2; Al_2O_3	(undisclosed)	Different but meet the requirement and does not raise new issues of SE.
Model	8 colors (Ultra transparently white, Transparently	multi colors (White, 16 A-D shades, and 3 Bleach	multi colors (White, and multiple shades for Light, Medium and	***Equivalent*** All the devices have multi colors of white

	white, Light, Intermediate, Dark, Ultra-high transparently white, Light gradient, Dark gradient)	shades)	Intense)	and customized shades. The subject device is met the requirement and the difference of shades does not raise new issues of SE.
Flexural Strength	> 800 MPa	> 800 MPa	> 800 MPa	***Same***
Sterile	Non-sterile	Non-sterile	Non-sterile	***Same***
Main compliance	ISO 6872	ISO 6872	(undisclosed)	***Same***

12. Similarity and Difference

The HCG Zirconia Ceramic Block is compared with *NexxZr™ S and NexxZr™ T* and *Copran Zr/Origin YZ*. The subject device has same intended use and technology/mechanism of action, and similar safety and performance as the predicate and reference devices. Although there are some different specifications between these devices, the performance test was completed and demonstrated similar test results. The subject device has also undergone safety and performance tests, and the results complied with the test requests. Therefore, the differences between the subject device and the predicate and reference devices do not raise any problem of substantial equivalence. The subject device is substantially equivalent to the predicate and reference devices in intended use, design and performance claims.

13. Conclusion

After analyzing non-clinical laboratory studies and testing data, it can be concluded that the HCG Zirconia Ceramic Block is substantially equivalent to the predicate and reference devices.