

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 <u>Federal Register</u>.

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-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/training-and-continuing-education/cdrh-learn) 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">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

510(k) Number (if known)

Form Approved: OMB No. 0910-0120 Expiration Date: 06/30/2023

See PRA Statement below.

| 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. | | | |
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| Type of Use (Select one or both, as applicable) | | | |
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| CONTINUE ON A SEPARATE PAGE IF NEEDED. | | | |

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510(k) SUMMARY

1. Type of Submission: Traditional

2. <u>Date of Summary:</u> 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. <u>Identification of the Device:</u>

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. <u>Identification of the Predicate Device:</u>

Predicate Device Name: NexxZrTM S and NexxZrTM 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. <u>Indications for Use / Intended Use of the Device</u>

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. <u>Description of the Device</u>

"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 | After aging, the test results | |
| | | strength, Chemical extraction, and | met the pre-defined criteria | |
| | | Coefficient of linear expansion. | according to the test standards. | |
| | ISO 6872 | | Thus the shelf life of the | |
| | 150 08/2 | | device is verified to | |
| | | | demonstrate substantial | |
| | | | equivalence. | |
| Biocompatibility | ISO 10993-5 | In Vitro Cytotoxicity Test, | All the test results met the | |
| | | Hemolysis Test, Acute Systemic | pre-defined criteria according | |
| | ISO 10993-4 | Toxicity Study, Skin Sensitization | to the test standards. Thus the | |

| | ISO 10993-11 | Study, White Rabbit | biocompatibility of the device | |
|------------|--------------|-----------------------------------|--------------------------------|--|
| | | Intracutaneous Reactivity Test, | is verified to demonstrate | |
| | ISO 10993-10 | White Rabbit Pyrogen Test, | substantial equivalence. | |
| | USP <151> | Muscle Implant Study, and | | |
| | | Repeated Dose 90-Day | | |
| | ISO 10993-6 | Subchronic Oral Toxicity Study in | | |
| | | Rat | | |
| Functional | ISO 6872 | Production quality of zirconia | All the test results met the | |
| testing | | ceramic block, Size measurement | pre-defined criteria according | |
| | | of supporting shaft, and Efficacy | to the test standards, so the | |
| | ISO 13356 | of the subject, predicate and | efficacy of the subject device | |
| | | reference devices (basic physical | is verified. The comparative | |
| | CN 12 12002 | and chemical characteristics) | testing of efficacy is also | |
| | CNS 13983 | | conducted on all devices, and | |
| | | | the test results demonstrate | |
| | CNS 13958 | | 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 |
|------------|------------------|--|----------------------|------------------------|
| Trade Name | HCG Zirconia | NexxZr TM S and | Connen 7n/Onioin V7 | |
| Trade Name | Ceramic Block | NexxZr TM T Copran Zr/Origin YZ | | Equivalence Discussion |
| 510(k) No. | K193090 | K130991 | K092496 | Discussion |
| Indication | HCG Zircon | a NexxZr TM are | Copran Zr/ Origin YZ | Equivalent |
| For Use / | Ceramic Block as | intended for the | Zirconia blanks are | All the devices are |

| Intended Use intended for the fabrication and fabrication and preparation of copings and full anatomical/full contour crowns, bridges, inlays, and onlays for anterior and posterior asegment restorations. Shape Shape Shape Tound blocks (disks) and square blocks Tounds bridges Tounds bridges Tounds blocks (disks) and square blocks Tounds bridges Tounds bridges Tounds blocks (disks) and square blocks Tounds bridges Tounds | | | | | |
|--|--------------|------------------------------------|---|-----------------------------|---------------------------|
| preparation of copings and full anatomical/full contour crowns, bridges, inlays, and bridges, inlays, and onlays for anterior and posterior segment restorations. Same a share of one pontic having a premolar width and square blocks (disks) and square blocks Main component Model (Ultra transparently) Provents of the preparation of copings and full anatomical/full anatomical/full contour crowns, bridges, inlays, and polycrystalline bridges, inlays, and onlays for anterior and posterior area segment restorations. Main component Provents of the preparation of copings and full anatomical/full anatomical/full contour crowns, bridges, inlays, and onlays for anterior and posterior area segment restorations. Main component Provents of the province have the same share of the crowns, bridges, inlays, and onlays for anterior crowns, bridges, inlays, and onlays for anterior and polycrystalline Main component Provents of the reference device has more specific usages on the crowns, bridges and veneers, the usage scope of subject device is same as that of predicate device is and telescopic crowns and telescopic | Intended Use | intended for the | fabrication and | presintered blanks for CAD | zirconia blocks and used |
| copings and full anatomical/full contour crowns, bridges, inlays, and onlays for anterior and posterior and posterior segment restorations. Copings and full anatomical/full contour crowns, bridges, inlays, and onlays for anterior and posterior and posterior segment restorations. Copings frameworks in the anterior and posterior areas | | fabrication and | preparation of | CAM or manual milling, | for preparation of dental |
| anatomical/full contour crowns, bridges, inlays, and onlays for anterior and posterior segment restorations. Crown friameworks in the anterior and posterior areas are than of product and posterior areas and telescopic crowns and telescopic crowns and telescopic crowns and telescopic areas Primary conical crowns and telescopic crowns and telescopic areas are premolar width Inlays, Onlays, Veneers | | preparation of | copings and full | made from biocompatible, | crowns, bridges, inlays, |
| contour crowns, bridges, inlays, and onlays for anterior and posterior segment restorations. Milling blanks designed for: | | copings and full | anatomical/full | tetragonal and | and onlays. Although |
| bridges, inlays, and onlays for anterior and posterior segment restorations. Application on the component Caro2; Y2O3; Al2O3 | | anatomical/full | contour crowns, | polycrystalline | the reference device has |
| onlays for anterior and posterior segment restorations. - Crown friameworks in the anterior and posterior areas - Bridge frameworks 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 - Cantilevered bridges with a max of one pontic having a premolar width - Inlays, Onlays, Veneers - Main component - ZrO ₂ ; Y ₂ O ₃ ; Al ₂ O ₃ - ZrO ₂ ; Y ₂ O ₃ ; HfO ₂ ; Al ₂ O ₃ - Requivalent - 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 - Requivalent - Both subject device and reference device and reference device have the same shape. - Different but meet the requirement and does not raise new issues of SE. - Requivalent - White, 16 A-D - White, and multiple shades - All the devices have | | contour crowns, | bridges, inlays, and | zirconiumdioxyde. | more specific usages on |
| and posterior segment restorations. - Crown friameworks in the anterior and posterior areas - Bridge frameworks 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 Shape | | bridges, inlays, and | onlays for anterior | Milling blanks designed | the crowns, bridges and |
| segment restorations. the anterior and posterior areas Firinge frameworks in the anterior and device. Thus the differences between subject and reference devices does not raise new issues of SE. Shape round blocks (disks) and square blocks Al2O3 | | onlays for anterior | and posterior | for: | veneers, the usage scope |
| 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 Tound blocks (disks) and square blocks Main component Main component Requivalent Al2O3 Posterior areas Primary conical crowns and telescopic crowns Pontic having a premolar width Inlays, Onlays, Veneers Equivalent Both subject device and reference device and reference devices does not raise new issues of SE. Bequivalent Both subject device and reference device have the same shape. Tound blocks (disks) and square blocks Main component Main component Requivalent Undisclosed) Beguivalent Undisclosed Fequivalent White, 16 A-D White, 16 A-D White, and multiple shades All the devices have | | and posterior | segment restorations. | - Crown friameworks in | of subject device is |
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| the anterior and device. Thus the posterior areas - Primary conical crowns and telescopic crowns and telescopic crowns and telescopic crowns with a max. of one pontic having a premolar width - Inlays, Onlays, Veneers Thus the differences between subject and reference devices does not raise new issues of SE. Primary conical crowns and telescopic crowns and telescopic crowns with a max. of one pontic having a premolar width - Inlays, Onlays, Veneers Primary conical crowns and reference devices does not raise new issues of SE. Primary conical crowns and reference devices does not raise new issues of SE. Primary conical crowns and telescopic crowns and telescopi | | | | posterior areas | reference device and the |
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| Shape Tound blocks (disks) and square blocks Main component Agro2; Y2O3; Al2O3 B colors Model Output B colors Model Al2O3 Primary conical crowns and telescopic and reference device have income is subject and reference device so su | | | | the anterior and | device. Thus the |
| Adain component Main component Main component Model According the specific crowns and telescopic crowns with a max. of one pontic having a premolar width a | | | | posterior areas | differences between |
| Shape Tound blocks (disks) and square blocks Tomponent Main component Model Algos Book scolors Model Cantilevered bridges with a max. of one pontic having a premolar width Inlays, Onlays, Veneers Main component Tround blocks (disks) and square blocks Tround blocks (disks) and square blocks Main component Tround blocks (disks) and square blocks Tround blocks (disks) and square blocks Misks Misks Main component Tround blocks (disks) and cylinders. Model Tround blocks (disks) and square blocks Misks Main component Tround blocks (disks) and square blocks Misks Misks Main cylinders. Misks Misks | | | | - Primary conical crowns | subject and reference |
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| Shape Tound blocks (disks) and square blocks Main component Model A colors Model Tound blocks (disks) and square blocks Tound blocks (disks) and square blocks Alaboa Misks Alaboa Alaboa Tound blocks (disks) and cylinders. May be disks, cubes, bars, and cylinders. May be disks, cubes, bars, and cylinders. May be disks, cubes, bars, and cylinders. Fequivalent (undisclosed) Fequivalent (undisclosed) Fequivalent (undisclosed) Fequivalent (White, and multiple shades All the devices have | | | | with a max. of one | |
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| Shape round blocks (disks) and square blocks disks and cylinders. Both subject device and reference device have the same shape. Main component ZrO2; Y2O3; Al2O3 ZrO2; Y2O3; HfO2; Al2O3 (undisclosed) Different but meet the requirement and does not raise new issues of SE. 8 colors multi colors multi colors Equivalent Model (Ultra transparently (White, 16 A-D) (White, and multiple shades All the devices have | | | | - Inlays, Onlays, Veneers | |
| Shape and square blocks disks and cylinders. reference device have the same shape. Main component ZrO ₂ ; Y ₂ O ₃ ; Al ₂ O ₃ ZrO ₂ ; Y ₂ O ₃ ; HfO ₂ ; Al ₂ O ₃ (undisclosed) Different but meet the requirement and does not raise new issues of SE. 8 colors multi colors multi colors Equivalent Model (Ultra transparently (White, 16 A-D) (White, and multiple shades All the devices have | | | | | Equivalent |
| $ \begin{array}{c ccccccccccccccccccccccccccccccccccc$ | C1 | disks | | may be disks, cubes, bars, | Both subject device and |
| $ \begin{array}{cccccccccccccccccccccccccccccccccccc$ | Snape | | | and cylinders. | reference device have |
| $ \begin{array}{c ccccccccccccccccccccccccccccccccccc$ | | | | | the same shape. |
| $ \begin{array}{c ccccccccccccccccccccccccccccccccccc$ | | | | | Different but meet the |
| component Al ₂ O ₃ not raise new issues of SE. 8 colors multi colors multi colors <i>Equivalent</i> Model (Ultra transparently (White, 16 A-D (White, and multiple shades All the devices have | Main | 7.0 . V.O. A1.0 | ZrO ₂ ; Y ₂ O ₃ ; HfO ₂ ; | (1' - 1 | requirement and does |
| 8 colors multi colors multi colors Equivalent Model (Ultra transparently (White, 16 A-D) (White, and multiple shades All the devices have | component | $ZrO_2; Y_2O_3; Al_2O_3$ Al_2O_3 | Al_2O_3 | (undisclosed) | not raise new issues of |
| Model (Ultra transparently (White, 16 A-D) (White, and multiple shades All the devices have | | | | | SE. |
| | | 8 colors | multi colors | multi colors | Equivalent |
| white, Transparently shades, and 3 Bleach for Light, Medium and multi colors of white | Model | (Ultra transparently | (White, 16 A-D | (White, and multiple shades | All the devices have |
| | | white, Transparently | shades, and 3 Bleach | for Light, Medium and | multi colors of white |

| | white, Light, | shades) | Intense) | and customized shades. |
|------------|----------------------|-------------|---------------|--------------------------|
| | Intermediate, Dark, | | | The subject device is |
| | Ultra-high | | | met the requirement and |
| | transparently white, | | | the difference of shades |
| | Light gradient, Dark | | | does not raise new |
| | gradient) | | | issues of SE. |
| Flexural | > 800 MPa | > 800 MPa | > 800 MPa | C |
| Strength | > 800 MPa | > 800 MPa | > 800 MPa | Same |
| Sterile | Non-sterile | Non-sterile | Non-sterile | Same |
| Main | ISO (972 | 150 (972 | (4: - 1 4) | C |
| compliance | ISO 6872 | ISO 6872 | (undisclosed) | Same |

12. Similarity and Difference

The HCG Zirconia Ceramic Block is compared with $NexxZr^{TM}$ S and $NexxZr^{TM}$ 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.