May 25, 2023

Shenzhen UP3d Technology Co., Ltd.
Judy Zhang
Head of Firm
401, Block B, Nanshan Yungu Nanfeng Tower 4093
Liuxian Avenue, Nanshan District
Shenzhen, Guangdong 518055
CHINA

Re: K230259
Trade/Device Name: Soreal Press, Soreal CAD
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: April 13, 2023
Received: April 25, 2023

Dear Judy Zhang:

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 -S

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)*

K230259

Device Name
Soreal CAD
Soreal Press

Indications for Use *(Describe)*

Soreal Press is indicated for single-unit anterior or posterior prostheses and for three-unit prostheses, such as veneers, inlay/onlay, partial crowns, anterior crowns, posterior crowns, using the hot press technique.
Soreal CAD is indicated for single-unit anterior or posterior prostheses and for three-unit prostheses, such as veneers, inlay/onlay, partial crowns, anterior crowns, posterior crowns, using the CAD/CAM system.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary - K230259

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date:

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	Shenzhen UP3d Technology Co., Ltd.
Address:	401, Block B, Nanshan Yungu Nanfeng Tower
	4093 Liuxian Avenue, Nanshan District, Shenzhen, China
Contact person:	Judy Zhang
Title:	Head of Firm
E-mail:	zhangwanlin@up3d.cn
Tel:	086-13713634397

2. Device Identification

Device/Trade Name:	Soreal Press/Soreal CAD
Regulation Number:	872.6660
Regulation Class:	Class 2
Product Code:	EIH
Common Name:	Powder, Porcelain

3. Predicate Device

510(K) number:	K192231
Device Name:	Dental Glass Ceramics Blocks
Manufacturer:	Aidite (Qinhuangdao) Technology Co., Ltd.
Regulation Number:	872.6660
Regulation Class:	Class 2
Product Code:	EIH
Common Name:	Powder, Porcelain

4. Device Description

Our products are divided into Soreal Press and Soreal CAD.

Soreal Press is put into the porcelain casting furnace and form it by hot pressing at 915-930 ℃, and treatment by sandblasting and glazing.

Soreal CAD is cut by grinding equipment with wet processing, and put into the porcelain casting furnace at 840-850℃ for 30 min to secondary crystallization treatment. Then dye it.

They are all composed of SiO_2, Li_2O, K_2O, P_2O_5, Al_2O_3 and other oxides. They have a variety of colors, and users can choose the right color to match the patient's natural teeth. In general, our products are also called Dental glass ceramic.

5. Indication for use

Soreal Press is indicated for single-unit anterior or posterior prostheses and for three-unit prostheses, such as veneers, inlay/onlay, partial crowns, anterior crowns, posterior crowns, using the hot press technique.

Soreal CAD is indicated for single-unit anterior or posterior prostheses and for three-unit prostheses, such as veneers, inlay/onlay, partial crowns, anterior crowns, posterior crowns, using the CAD/CAM system.

6. Comparison to Predicate Device

Compared to the predicate devices, the subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device as summarized in the following table

SE Comparisons	Proposed Devices K230259		Predicate Device K192231	Similarities/ Differences
Name	Soreal Press	Soreal CAD	Dental Glass Ceramics Blocks	/
Classification	Class 2	Class 2	Class 2	Same
Indications for Use	Soreal Press is indicated for single-unit anterior or posterior prostheses and for three-unit prostheses, such as veneers, inlay/onlay, partial crowns, anterior crowns, posterior crowns, using the hot press technique.	Soreal CAD is indicated for single-unit anterior or posterior prostheses and for three-unit prostheses, such as veneers, inlay/onlay, partial crowns, anterior crowns, posterior crowns, using the CAD/CAM system.	Dental Glass Ceramics Blocks are indicated for fabricating all-ceramic restorations such as veneers, inlay/onlay, partial crowns, anterior crowns, posterior crowns, using the hot press technique or CAD/CAM system	Similar Note 1
Materials	SiO_2, Li_2O, K_2O, P_2O_5, Al_2O_3 and other oxides	SiO_2, Li_2O, K_2O, P_2O_5, Al_2O_3 and other oxides	SiO_2, Li_2O, K_2O, Al_2O_3 and other oxides	Similar Note 2
Processing at Dental lab	Hot Press (Soreal Press)	CAD/CAM (Soreal CAD)	Hot Press (Up. Press Series) CAD/CAM (Up. CAD Series)	Same
Geometry	Cylinder	Cube	Blocks	Similar Note 3

Dimension	Various	Various	Various	Same
Single use	Yes	Yes	Yes	Same
Available color	Various	Various	Various	Same
Sterile	Non-sterile	Non-sterile	Non-sterile	Same
Uniformity	The colorants are dispersed uniformly throughout the dental ceramic material and in powdered ceramic products.	The colorants are dispersed uniformly throughout the dental ceramic material and in powdered ceramic products.	Meet the requirements of ISO 6872:2015	Same
Freedom of extraneous materials	Device shall be free from extraneous materials	Device shall be free from extraneous materials	Meet the requirements of ISO 6872:2015	Same
Radioactivity of dental ceramic	< 1.0Bq·g^{-1} of ^{238}U	< 1.0Bq·g^{-1} of ^{238}U	Meet the requirements of ISO 6872:2015	Same
Flexural Strength	>300MPa	>300MPa	Meet the requirements of ISO 6872:2015	Similar Note 4
Linear thermal expansion coefficient	(10±1.5)×10^{-6}K^{-1}	(10±1.5)×10^{-6}K^{-1}	Meet the requirements of ISO 6872:2015	Similar Note 5
Glass transition temperature	550±50 °C	550±50 °C	Meet the requirements of ISO 6872:2015	Similar Note 6
Chemical solubility	<100μg/cm^2	<100μg/cm^2	Meet the requirements of ISO 6872:2015	Similar Note 7

Density	Ceramic block density: 2.4 ~ 2.6 g/cm^3	Ceramic block Density: 2.3 ~ 2.6 g/cm^3 Density of porcelain block after sintering: 2.4 ~ 2.7 g/cm^3	Meet the requirements of ISO 6872:2015	Similar Note 8
In Vitro Cytotoxicity Test (ISO 10993-5:2009)	No Cytotoxicity effect		No Cytotoxicity effect	Same
Irritation Oral Mucosa Irritation (ISO 10993-10:2010)	Not a primary oral mucosa irritant under the conditions of the study		Not a primary oral mucosa irritant under the conditions of the study	Same
Skin Sensitization (ISO 10993-10:2010)	Not a sensitizer under the conditions of the study		Not a sensitizer under the conditions of the study	Same
Subacute and Subchronic Toxicity (ISO 10993-11:2017)	No subacute and subchronic toxic effects observed		No subacute and subchronic toxic effects observed	Same
Genotoxicity (ISO10993-3:2014)	No genotoxic effects observed		No genotoxic effects observed	Same
Acute Systemic Toxicity (ISO 10993-11:2017)	No acute Systemic Toxicity		/	Different Note 1
Pyrogen (ISO 10993-11:2017)	Meets the requirements for the absence of pyrogens		/	Different Note 2

Tips: “/” means that it cannot be applicable.

Similar Note 1: Although their Indications for Use is not same, they all meet the requirement of ISO 6872. So, this difference will not increase risk and affect the effectiveness and safety of the device.

Similar Note 2: Although their composition may be slightly different, their main composition is SiO_2, Li_2O and K_2O, and both meet the requirements of ISO 6872:2015. Their chemical and physical properties are basically the same and will not affect the safety and effectiveness of the device.

Similar Note 3: Since the shape of the equipment can be customized in subsequent processing, the shape will not affect the safety and effectiveness of the device.

Similar Note 4: The Flexural Strength of devices is similar. But both products meet the requirements of ISO 6872:2015. The standard requires that the Flexural Strength should be higher than 300MPa. The data gap does not affect the actual safety and effectiveness of the product. This similarity does not affect the substantial equivalence of the product.

Similar Note 5: According to ISO 6872:2015, the linear thermal expansion coefficient of the ceramics shall not deviate by more than $0.5 \times 10^{-6}\ K^{-1}$ from the value stated by the manufacturer. The linear thermal expansion coefficient of ceramics specified by us is $(10\pm1.5)\times10^{-6}K^{-1}$, and the test results of ISO 6872 show that the deviation does not exceed $0.5 \times 10^{-6}\ K^{-1}$. The linear thermal expansion coefficient declared by the predicate product also meets the requirements of ISO 6872:2015. So, the differences will not affect performance and safety of devices. This similarity does not affect the substantial equivalence of the product.

Similar Note 6: We cannot get the glass transition temperature of predicate device, so our device may be different from predicate device on glass transition temperature. According to ISO 6872:2015, the glass transition temperature of the ceramics shall not deviate by more than 20 °C from the value stated by the manufacturer. The glass transition temperature of ceramics specified by us is 550±50 °C, and the test results of ISO 6872 show that the deviation does not exceed 20 °C. The glass transition temperature declared by the predicate product also meets the requirements of ISO 6872:2015. So, the differences will not affect performance and safety of devices. This similarity does not affect the substantial equivalence of the product.

Similar Note 7: The Chemical solubility of devices is similar. But both products meet the requirements of ISO 6872:2015. The standard requires that the Chemical solubility should be less than 100 $\mu g/cm^2$. The data gap does not affect the actual safety and effectiveness of the product. This similarity does not affect the substantial equivalence of the product.

Similar Note 8: According to 6872:2015, the density is not necessary. We test the density. And the different density will not affect performance and safety of devices. This similarity does not affect the substantial equivalence of the product.

Different Note 1: Predicate Device did not test the Acute Systemic Toxicity. But we test the Acute Systemic Toxicity. The difference will not affect performance and safety of devices.

Different Note 2: Predicate Device did not test the Pyrogen. But we test the Pyrogen. The difference will not affect performance and safety of devices.

All the differences don't affect the safety and effectiveness which is concluded after all the required testing, so no safety and effectiveness issues relating to the system come into conclusion.

7. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

The Performance tests were performed according to ISO 6872:2015 Dentistry - Ceramic materials, and the test results showed that the proposed device meets the requirements specified in the standard (see the following Table)

Test Item	Requirements	Measured data		Conclusion
Uniformity	The colorants are dispersed uniformly throughout the dental ceramic material and in powdered ceramic products.	The colorants are dispersed uniformly throughout the dental ceramic material and in powdered ceramic products.		Pass
Freedom of extraneous materials	Device shall be free from extraneous materials	Device shall be free from extraneous materials		Pass
Linear thermal expansion coefficient	$(10\pm1.5)\times10^{-6}K^{-1}$	$11.1\times10^{-6}K^{-1}$		Pass
Glass transition temperature	550±50 °C	Soreal CAD: 518.4°C	Soreal Press: 515.8°C	Pass
Chemical solubility	<100μg/cm²	Soreal CAD (μg/cm²)	Soreal Press (μg/cm²)	Pass
		22.37	21.87	
		21.56	22.56	
		22.38	21.33	
		19.98	19.32	
		23.20	21.21	
		19.37	19.34	
		20.68	19.63	
		23.45	22.41	
		21.76	24.12	

		22.24	21.28	
Radioactivity of dental ceramic	< 1.0Bq·g^{-1} of 238U	<0.0073 Bq·g^{-1} of ^{238}U		Pass
Flexural Strength	>300MPa	Soreal CAD (MPa)	Soreal Press (MPa)	Pass
		389	410	
		367	398	
		388	386	
		365	405	
		378	421	
		386	436	
		377	397	
		398	392	
		423	427	
		385	379	

Biocompatibility testing was performed to verify the equivalent safety of the materials that are used.

The Biocompatibility tests were performed according to ISO 10933 Biocompatibility, and the test results showed that the proposed device meets the requirements specified in the standard (see the following Table)

Test Item	Requirements	Measured data	Conclusion
In Vitro Cytotoxicity Test (ISO 10993-5:2009)	No Cytotoxicity effect	No Cytotoxicity effect	Pass
Irritation Oral Mucosa Irritation (ISO 10993-10:2010)	Not a primary oral mucosa irritant under the conditions of the study	Not a primary oral mucosa irritant under the conditions of the study	Pass
Skin Sensitization (ISO 10993-10:2010)	Not a sensitizer under the conditions of the study	Not a sensitizer under the conditions of the study	Pass

Subacute and Subchronic Toxicity (ISO 10993-11:2017)	No subacute and subchronic toxic effects observed	No subacute and subchronic toxic effects observed	Pass
Genotoxicity (ISO10993-3:2014)	No genotoxic effects observed	No genotoxic effects observed	Pass
Acute Systemic Toxicity (ISO 10993-11:2017)	No acute Systemic Toxicity	No acute Systemic Toxicity	Pass
Pyrogen (ISO 10993-11:2017)	Meets the requirements for the absence of pyrogens	Meets the requirements for the absence of pyrogens	Pass

8. Conclusion

Information included in this premarket notification supports the substantial equivalence of the proposed Soreal Press/Soreal CAD. The proposed device has the identical intended use, identical indication for us, identical performance, identical fundamental technology, and identical biocompatibility as the predicate device K192231. The results of the testing support a determination of substantial equivalence.