March 15, 2024

Sincera Technology (Changchun) Co., Ltd.
% Eva Li
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.
Shanghai,
China

Re: K240112
Trade/Device Name: Light Cure Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: January 16, 2024
Received: January 16, 2024

Dear Eva Li:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

FDA Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., RAC, CQIA
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)*
K240112

Device Name
Light Cure Composite

Indications for Use *(Describe)*
Anterior restorations (Class III, IV)
Class V restorations (cervical caries, root erosion, wedge-shaped defects)
Restorations in the posterior region (Class I and II)
Veneering of discolored anterior teeth
Splinting of mobile teeth
Repair of composite and ceramic veneers

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. Information of the submitter:

Submitter's Name: Sincera Technology (Changchun) Co., Ltd.
Address: No. 177 Changda Rd, Hi-tech District, Changchun City, Jilin Province, P. R. China
Contact person: Tony Su

Tel：+8615143153582

Email：tony.su@sinceradental.com

Preparation Date: Jan 2nd, 2024

2. Basic information of the device

Classification Name: Material, Tooth Shade, Resin
Common / Usual Name: Tooth shade resin material.
Proprietary Name: Light Cure Composite
Product Code: EBF
Class: Class II
Regulation: 21 CFR 872.3690

3. Predicate Device

K042819
TETRIC EVOCERAM
VOCLAR VIVADENT, INC.

4. Indication for Use

Anterior restorations (Class III, IV)
Class V restorations (cervical caries, root erosion, wedge-shaped defects) Restorations in the posterior region (Class I and II)
Veneering of discolored anterior teeth
Splinting of mobile teeth
Repair of composite and ceramic veneers

5. Device Description

Light Cure Composite is a state-of-the-art light-curing, radiopaque, nano-hybrid composite for the restorative therapy. The device cures with light at the wavelength range of 400–500 nm (blue light). The device is paste contained in PP syringe.

6. Technological Characteristics Comparison:

Item	Subject device	Predicated device	Comparison
Device Name	Light Cure Composite	TETRIC VOCERAM	N/A
510(K) No.		K042819	N/A
Classification	Class II	Class II	Same
Regulation	21 CFR 872.3690	21 CFR 872.3690	Same
Indication for use	Anterior restorations	Anterior restorations (Class	Same

	(Class III, IV) Class V restorations (cervical caries, root erosion, wedge-shaped defects) Restorations in the posterior region (Class I and II) Veneering of discolored anterior teeth Splinting of mobile teeth Repair of composite and ceramic veneers	III, IV) Class V restorations (cervical caries, root erosion, wedge-shaped defects) Restorations in the posterior region (Class I and II) Veneering of discolored anterior teeth Splinting of mobile teeth Repair of composite and ceramic veneers	
Product Code	EBF	EBF	Same
Patient Population	All the groups	All the groups	Same
Prescription Use	Rx only	Rx only	Same
Environment	Dental prosthetics and authorized laboratories and clinics	Dental prosthetics and authorized laboratories and clinics	Same
Applicable Standards	ISO 4049; ISO 10993-1	ISO 4049; ISO 10993-1	Same
Device Sterilization	No	No	Same
Shelf life	2 years	3 years	Different*1
Light curing unit	Power: ≥ 400mW/cm2 Wavelength: 400-500nm Curing time:20s	Power: ≥500mW/cm2 Wavelength: 400-500nm Curing time:20s	Different*2
particle size	0.4-2μm	0.4-3μm	Different*3
Elastic Modulus(GPa)	Mean:8.5	Mean:7.4	Different*3
Compressive Strength(MPa)	Mean:286.5	Mean:248.4	Different*3
Surface Hardness(HV)	Mean:63.1	Mean:53.8	Different*3
Radio-opacity	Mean:2.27mm	Not provided	N/A

7. Non-clinical performance Data:

Test Item	Acceptance criterial	Result
Outward appearance-ISO 4049	According to visual 1nspect1on, the product should be uniform in texture and should be a paste without visible impurities and foreign matter.	Meet the requirement
Sensitivity to ambient light-ISO 4049	The material of sample remains physically homogeneous.	Meet the requirement
Depth of Cure-ISO 4049	≥1.5mm	≥1.5mm
Flexural strength-ISO 4049	≥80Mpa	≥80Mpa
Water sorption-ISO 4049	≤40μg/mm^3	≤40μg/mm^3
solubility-ISO 4049	≤7.5μg/mm^3	≤7.5μg/mm^3

Shade-ISO 4049	Without the need for a magnifying glass to observe with the naked eye, the cured material should be evently coloredk	Meet the requirement
Color comparison for color stability-ISO 4049	Only slight changes are allowed	Meet the requirement
Appearance of container-ISO 4049	Visually observe that the surface of the container should be smooth, without scratches, cracks, burrs, small notches or macroscopic defects caused by mechanical processing.	Meet the requirement
Delivery performance of container-ISO 4049	Remove the syringe cap and turn the container push rod clockwise allowing resin to be smoothly squeezed out of the syringe without obstruction	Meet the requirement
Compressive Strength	≥200 Mpa	Meet the requirement
Elastic Modulus	≥6 Gpa	Meet the requirement
Surface Hardness	≥60(HV)	Meet the requirement
particle size	0.4-2μm	
Radio-opacity	Mean: 2.27mm	

8. Biocompatibility

Meet ISO 10993-1 - Biological evaluation of medical devices — Part 1: Evaluation and testing.

9. Conclusion

The results of the testing described above provide reasonable assurance that the subject device is as safe and effective as the predicate device(s) which cleared under K042819 and supports a determination of substantial equivalence.