July 28, 2021

Nanchang Dental Bright Technology Co., Ltd
Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
CHINA

Re: K211489
Trade/Device Name: Dental Impression Material
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: May 26, 2021
Received: June 1, 2021

Dear Ivy Wang:

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 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)*
K211489

Device Name
Dental Impression Material

Indications for Use *(Describe)*
The Dental Impression Material is intended for use with all crowns, bridges, and orthodontic impression techniques to reproduce the structure of a patient's teeth and gums.

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."

Nanchang Dental Bright Technology Co., Ltd
Building 182, Jiahai Industrial Park, No. 2799, Tianxiang Avenue, High-Tech Zone,
Nanchang, Jiangxi, China

K211489 510(K) Summary

A. Applicant:

Nanchang Dental Bright Technology Co., Ltd
Address: Building 182, Jiahai Industrial Park, No. 2799, Tianxiang Avenue, High-Tech Zone, Nanchang, Jiangxi, China
Contact Person: Justin Qin
Tel: +86 15079010001
Mail: Justin@enjoywhite.com

Submission Correspondent:
Primary contact: Ms. Ivy Wang
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-58817802
Email: haiyu.wang@sungoglobal.com
Secondary contact: Mr. Raymond Luo
Room 1401, Dongfang Building, 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-68828050
Email: fda.sungo@gmail.com

B. Device:

Trade Name: Dental Impression Material
Common Name: Dental Impression Material

Regulatory Information
Classification Name: Material, Impression
Classification: Class II.
Product code: ELW
Regulation Number: 872.3660
Review Panel: Dental

C. Predicate device:

K201483
Impression Material
Zhengzhou Huaer Electro Optics Technology Co., Ltd.

D. Indications for use of the device:

The Dental Impression Material is intended for use with all crowns, bridges, and orthodontic impression techniques to reproduce the structure of a patient's teeth and gums.

E. Device Description:

The Dental Impression Material is a kind of addition-cure rubber impression material composed of vinyl polysiloxane and various fillers, with neutral smell and applicable to impression in dentistry.

The Dental Impression Material is very easy to mix and has good dimensional stability, helps to make precise impression taking.

F. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as same or similar to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- ISO 4823 Dentistry - Elastomeric impression materials

G. Clinical Test Conclusion

No clinical study is included in this submission.

H. Comparison with predicate device

Table 1 Comparison Table

Device	Predicate Device	Proposed Device	Result
Manufacturer	Zhengzhou Huaer Electro Optics Technology Co., Ltd	Nanchang Dental Bright Technology Co., Ltd	-
510K number	K201483	-	-
Model Name	Impression Material	Dental Impression Material	-
Classification	Class II Device, ELW (21 CFR 872.3660)	Class II Device, ELW (21 CFR 872.3660)	Same
Indications for use	Used for all crown, bridge, and orthodontic impression techniques.	The Dental Impression Material is intended for use with all crowns, bridges, and orthodontic impression techniques to reproduce the structure of a patient's teeth and gums.	Actually same indications described with different words.
Standard conformed	ISO4823	ISO4823	Same
Physical properties	- Classification according to ISO4823: Type 0 - Dimensional accuracy: Max.1.5% - Consistency: Max. 35mm	- Classification according to ISO4823: Type 0 - Dimensional accuracy: Max.1.5% - Consistency: Max. 35mm	Same

	- Compatibility with the die and cast materials: 75 ㎛ reproduction - Curve of the shrinkage (Strain in compression): Min.0.8 ~ Max.20%	- Compatibility with the die and cast materials: 75 ㎛ reproduction - Curve of the shrinkage (Strain in compression): Min.0.8 ~ Max.20%	
Raw Material	Vinyl polysiloxane	Vinyl polysiloxane	Same
Mixing Ratio	1:1	1:1	Same
Sterility	Non-sterile	Non-sterile	Same
Method of Manipulation	Hand-kneaded mixes	Hand-kneaded mixes	Same
Biocompatibility	ISO 10993	ISO 10993	Same

Table 2 Performance parameter

Item	Proposed device	Acceptance Criteria (Type 0)	Result
Consistency	32 mm	< 35mm	PASS
Compatibility with gypsum	Complied	< 75 um	PASS
Detail Reproduction	Complied	< 75 um	PASSS
Linear dimensional change %	0.72	< 1.5	PASS
Elastic recovery	98.23%	≥ 96.5%	PASS
Strain in compression %	4.41	0.8 ~ 20%	PASS

I. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K201483.