October 8, 2020

Zhengzhou Huaer Electro Optics Technology Co., Ltd
℅ Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
13th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
CHINA

Re: K201483
Trade/Device Name: Impression Material
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: September 8, 2020
Received: September 11, 2020

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201483

Device Name
Impression Material

Indications for Use *(Describe)*
Used for all crown, bridge, and orthodontic impression techniques.

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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"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."

K201483

510(K) Summary

Date of Summary prepared: 2020-10-02

A. Applicant:

Zhengzhou Huaer Electro Optics Technology Co., Ltd
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B. Device:

Trade Name: 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:

K152518
Vonflex S™ Putty
VERICOM Co., Ltd.

D. Intended use of the device:

Used for all crown, bridge, and orthodontic impression techniques.

E. Device Description:

The 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.

It consists of base and catalyst, in which putty base contains Vinyl polysiloxane, Methylhydrogensiloxane dimethylsiloxane, dimeticone, white oil and silicon.

Catalyst mainly contains vinyl polysiloxane, platinum catalyst, dimeticone, white oil and silicon.

The product is provided non-sterile.

F. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) 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 10993-11 Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity
- 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	**Proposed Device**	**Predicate Device**	**Result**
Manufacturer	Zhengzhou Huaer Electro Optics Technology Co., Ltd	VERICOM Co., Ltd.	-
510K number	K201483	K152518	-
Model Name	Impression Material	Vonflex S™ Putty	-
Classification	Class II Device, ELW (21 CFR 872.3660)	Class II Device, ELW (21 CFR 872.3660)	Same
Intend use	Used for all crown, bridge, and orthodontic impression techniques.	It is used for all crown, bridge and orthodontic impression techniques.	Same
Standard conformed	ISO4823	ISO4823	Same
Physical properties	- Classification according to ISO4823: Type 0 - Dimensional accuracy: Max.1.5% - Consistency: Max. 35mm - Compatibility with the die and cast materials: 75 ㎛	- Classification according to ISO4823: Type 0 - Dimensional accuracy: Max.1.5% - Consistency: Max. 35mm - Compatibility with the die and cast materials: 75 ㎛	Same

	reproduction - Curve of the shrinkage (Strain in compression): Min.0.8 ~ Max.20%	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 the die and cast materials	Complied	< 75 um reproduction	PASS
Linear dimensional change %	0.69	< 1.5	PASS
Elastic recovery	97.73%	≥ 96.5%	PASS
Strain in compression %	4.52	0.8 ~ 20%	PASS

I. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is substantial equivalence with the legally marketed predicate device, Vonflex S™ Putty under K152518.