



August 8, 2022

Chemoment Materials Co.,ltd
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Century Avenue
Shanghai, 200122
China

Re: K221668

Trade/Device Name: Dental Impression Material
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: June 8, 2022
Received: June 8, 2022

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 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

Indications for Use

Submission Number (if known)

K221668

Device Name

Dental Impression Material (Type 0)

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.

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K221668

510(K) Summary

(As requirement by 21 CFR 807.92)

Date prepared: 26th, May, 2022

A. Applicant:

Name: Chemoment Materials Co.,ltd

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Submission Correspondent:

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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: 21 CFR 872.3660

Review Panel: Dental

C. Predicate device:

K211489

Nanchang Dental Bright Technology Co., Ltd.

Trade Name: Dental Impression Material

Common Name: Dental Impression Material

Regulatory Information

Classification Name: Material, Impression

Classification: Class II

Product code: ELW

Regulation Number: 21 CFR 872.3660

Review Panel: Dental

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 which 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 complied with the following standards:

- ISO 10993-05:2009 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 4823:2021 Dentistry - Elastomeric impression and bite registration materials

Performance parameters are summarized in below Table 1.

Table 1 Performance Parameter

Item	Proposed device	Acceptance criteria (Type 0)	Result
Consistency	31.8mm	≤35mm	Pass
Compatibility with gypsum	Complied	75μm	Pass
Detail reproduction	Complied	75μm	Pass
Linear dimensional change	0.798%	≤1.5%	Pass
Elastic recovery	97.718%	≥96.5%	Pass
Strain in compression	5.44%	0.8~20%	Pass

G. Clinical Test Conclusion

No clinical study is included in this submission.

H. Comparison with predicate device

Table 2 Comparison of Proposed and Predicate Devices

Device	Proposed Device	Predicate Device	Result
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510K #	K221668	K211489	-
Manufacturer	Chemoment Materials Co.,ltd	Nanchang Dental Bright Technology Co., Ltd.	-
Product Name	Dental Impression Material	Dental Impression Material	Same
Classification	Class II Device, ELW (21 CFR 872.3660)	Class II Device, ELW (21 CFR 872.3660)	Same
Indications for use	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.	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.	Same
Standard conformed	ISO 4823	ISO 4823	Same
Physical properties	-Classification according to ISO 4823: Type 0 -Dimensional accuracy: Max. 1.5% -Consistency: Max.35mm -Compatibility with the die and cast materials:75µm reproduction -Curve of the shrinkage (strain in compression): Min.0.8-Max.20%	-Classification according to ISO 4823: Type 0 -Dimensional accuracy: Max. 1.5% -Consistency: Max.35mm -Compatibility with the die and cast materials:75µm reproduction -Curve of the shrinkage (strain in compression): Min.0.8-Max.20%	Same
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

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K211489.