May 23, 2024

Kulzer, LLC
David Vincent
Director, QA/RA
4315 S. Lafayette Blvd
South Bend, Indiana 46614

Re: K233868
Trade/Device Name: dima Print Teeth & Temp
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG, POW, PZY
Dated: December 6, 2023
Received: May 2, 2024

Dear David Vincent:

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,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, 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.

Submission Number *(if known)*

K233868

Device Name

dima Print Teeth & Temp

Indications for Use *(Describe)*

Photopolymer for 3D printing of individualized, provisional and permanent prosthetic works.
Indications
- Long-term temporary restorations (up to 6 months),
- Teeth for removable dentures

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) #: K233868

510(k) Summary

Prepared on: 2024-05-02

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Kulzer, LLC
Applicant Address	4315 S. Lafayette Blvd South Bend IN 46614 United States
Applicant Contact Telephone	(574) 299-5421
Applicant Contact	Mr. David Vincent
Applicant Contact Email	David.Vincent@kulzer-dental.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	dima Print Teeth & Temp
Common Name	Temporary crown and bridge resin
Classification Name	Crown And Bridge, Temporary, Resin
Regulation Number	872.3770
Product Code	EBG

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K192806	DENTCA Crown and Bridge	EBG
K172398	DENTCA Denture Teeth	PZY

Device Description Summary

21 CFR 807.92(a)(4)

dima Print Teeth & Temp is a photopolymer liquid for 3D printing of dental appliances. Its processing by dental healthcare professionals includes 3D printing, cleaning and curing. The final product produced by dental healthcare professionals will be an individual medical device for a special patient, inserted into the oral cavity, adapted and connected to the remaining residual teeth or functionally adapted to a given denture. Dima Print Teeth & Temp is offered in a range of colors.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Photopolymer for 3D printing of individualized, provisional and permanent prosthetic works.
Indications
- Long-term temporary restorations (up to 6 months),
- Teeth for removable dentures

Indications for Use Comparison

21 CFR 807.92(a)(5)

In comparison to the predicate devices, the device dima Print Teeth & Temp combines the indications of both of the predicate devices (see predicate comparison table). This does not constitute a new intended use.

Technological Comparison 21 CFR 807.92(a)(6)

In comparison to the predicate devices, the device dima Print Teeth & Temp has the same technological characteristics as the predicate devices. Therefore, both dima Print Teeth & Temp and the predicates can be considered substantially equivalent.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Testing of the physical characteristics as listed in the predicate comparison table was conducted to evaluate the performance of dima Print Teeth & Temp, according to requirements of ISO 10477 and ISO 22112. All requirements were met. Please see the attachment below for detailed nonclinical testing performed.

Not Applicable.

Testing of the physical characteristics as listed in the predicate comparison table was conducted to evaluate the performance of dima Print Teeth & Temp, according to requirements of ISO 10477 and ISO 22112. All requirements were met.