



October 15, 2024

Shenzhen Piocreat 3D Technology Co., Ltd.
% Youshan Gong
RA Specialist
Feiyong Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90,
Qianhai Road
Shenzhen, Guangdong 518052
CHINA

Re: K241673

Trade/Device Name: Denture Base Resin (PN-Denture (Red, White))
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBG, PZY, ELM, EBI
Dated: September 19, 2024
Received: September 19, 2024

Dear Youshan Gong:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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

Indications for Use

Submission Number (if known)

K241673

Device Name

Denture Base Resin (PN-Denture (Red, White))

Indications for Use (Describe)

Denture Base Resin is a light-curable resin indicated for the fabrication of:

- individual and fixed permanent full single crowns, permanent partial crowns in front and posterior area
- denture bases

Denture Base Resin is intended exclusively for professional dental work.

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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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

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Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Denture Base Resin (PN-Denture (Red, White))
Common Name	Tooth shade resin material
Classification Name	Material, Tooth Shade, Resin
Regulation Number	872.3690
Product Code(s)	EBF, EBI, EBG, PZY, ELM

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K210977	E-Dent 1000	EBF
K220771	Stratasys TrueDent	EBF

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Denture Base Resin is an alternative to traditional heat cured and auto polymerization resins. The resins are available in two (2) different colors (white, red). Denture Base Resin can be used with PioNext D Series. PioNext D Series printers include a 3D printing system that utilizes Digital Light Process (DLP) technology, with automatic feeding process, and a UV LED (405nm) curing process. The dental appliance is then cured in the PioNext UV-02 curing chamber and sent back to the dentist for try-in and final adjustment.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

Denture Base Resin is a light-curable resin indicated for the fabrication of:

- individual and fixed permanent full single crowns, permanent partial crowns in front and posterior area
- denture bases

Denture Base Resin is intended exclusively for professional dental work.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The subject device and predicate devices have the same indications for use.

Though the Indications for Use of subject device is little different from the predicate device, the main difference is that the subject device is indicated for denture bases which is not included in the indications of the primary predicate but is addressed by the reference device. The Indications for Use for both the subject device and primary predicate include statements that the material is an alternative to

traditional light-curable resin and is intended exclusively for professional dental work. Both the subject device and primary predicate require fabrication of these devices using a computer aided design and manufacturing (CAD/CAM) system. The subject device Indications for Use Statement does not list the process components, as it is not necessary that such components be listed in the Statement. Thus, this difference is insignificant and do not raise any safety or effectiveness problems.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The subject device and predicate devices have the same technological characteristics, the subject device conduct performance test, it can comply with ISO 10477, and ISO 20795, ISO 7491, ISO 4049, guidance "Denture Base Resins - Performance Criteria for Safety and Performance Based Pathway: Guidance for Industry and Food and Drug Administration Staff".

The technological characteristics such as mechanical and biological properties, printing technology, chemical description, material type, cutting method, product state, product characteristics, and workflow are similar to the predicate device. Any minor differences between the subject device and the listed predicate device do no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate device for its intended use.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Non-clinical: We conducted the Denture Base Resin Performance test, including ☒Surface quality, ☒Dimensional stability, ☒Color and color stability, ☒Translucency, ☒Flexural strength and flexural modulus, ☒Freedom from porosity, ☒Water Sorption, ☒Water Solubility, and we also conducted the Verification Report of Cleaning and Disinfection Tolerance. The subject device can meet the requirements.

Clinical test: Not Applicable.