December 23, 2024

Riton 3D Technology Co., Ltd
Reanny Wang
General Manager
Room C101, Building 2, No. 21, Hejing South Road
Liwan District
Guangzhou, Guangdong 51038
China

Re: K243103
Trade/Device Name: Denture Base
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: September 25, 2024
Received: September 30, 2024

Dear Reanny 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 (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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243103

Device Name

Denture Base

Indications for Use *(Describe)*

Denture Base resin is a light-curable polymerizable resin intended to be used for the fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional denture base material.

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.

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510(K) SUMMARY

Denture Base (K243103)

Submitter: Riton 3D Technology Co., Ltd
Room C101, Building 2, No. 21, Hejing South Road, Liwan District Guangzhou,Guangdong CN 51038
Phone: +86-20-81509265
Contact Person: YongMing Sun
Date Prepared: Sep. 25, 2024
Name of Device: Denture Base
Common or Usual Name: Denture Base, Prescription
Classification Name: Resin, Denture, Relining, Repairing, Rebasing
Regulation Description: Denture relining, repairing, or rebasing resin
Device Class: Class 2
Regulation Number: 21 CFR 872.3760
Product Code: EBI
Primary Predicate Device: SprintRay High Impact Denture Base(K221678)

Device Description:

Fabrication of dental prosthetics with Denture Base resin requires computer-aided design and manufacturing system that includes the following components not part of the device: oral casting impression, digital denture base file created in an optical impression system, 3D printer, and curing light equipment.

The Denture Base consists of a curable dental acrylate resin that is designed to be used in conjunction with a scanned 3D image of a patient's teeth, and 3D printer assembly, to locally manufacture out a dental appliance in dental offices based on the clinician's judgment of patient need.

Denture Base resin is intended exclusively for professional dental work.

Denture Base is designed to meet appropriate ISO standards for flexibility, sorption, and solubility to withstand prolonged use in the oral cavity. It is delivered non-sterile, and instructions are provided on cleaning the material prior to providing it to a patient. Curing is performed with a UV lamp. The appliance is then cleaned, trimmed, and verified to fit in the dental office before the patient leaves.

Intended Use / Indications for Use

Denture Base resin is a light-curable polymerizable resin intended to be used for the fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional denture base material.

Summary of Technological Characteristics

Light curing of a 3D printed acrylate resin is the technological principle for both the subject and predicate devices. The Denture Base is poured into a 3D printer, which relies on scanned images of the patient's oral cavity to produce a dental appliance.

The following technological differences exist between the subject and predicate devices:

- Differences in acrylate resin material

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for Denture Base was conducted in accordance with the International Standard ISO 10993-1, as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Genotoxicity
- Acute Systematic Toxicity
- Subchronic toxicity
- Irritation
- Sensitization

Denture Base is categorized as Surface Devices in contact with mucosal membrane with a contact duration of long time>30 days

Bench Testing

Denture Base was tested for conformity with the industry consensus standard ISO 20795-1. The battery of testing included the following tests:

- Ultimate Flexural Strength and Modulus
- Water Sorption and Solubility
- Residual Methyl Methacrylate Monomers
- Homogeneity
- Surface Characteristics
- Shape Capability
- Translucency, and Polishability
- Colour
- Freedom from Porosity
- Color Stability
- Maximum stress intensity factor
- Total fracture work
- Bonding to synthetic polymer teeth

In all instances, Denture Base functioned as intended and the outcomes were as expected.

Equivalence to Marketed Devices

Feature	Subject Device (K243103)	Primary Predicate Device (K221678)	Comparison
Product Name	Denture Base	SprintRay High Impact Denture Base	N/A
Product Code	EBI	EBI	Same
Regulation	21 CFR 872.3760	21 CFR 872.3760	Same
Indications for Use/Intended Use	Denture Base resin is a light-curable polymerizable resin intended to be used for the fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional denture base material.	The SprintRayHigh Impact Denture Base resin is a light-curable polymerizable resin intended to be used for the fabrication and repair, of full and partial removable dentures and baseplates. The material is an alternative to traditional denture base material.	Same
User Population	Clinicians in dental offices	Clinicians in dental offices	Same
Chemical Description	Methacrylate-based resin	Methacrylate-based resin	Similar
Material Type	Light-curable Resin	Light-curable Resin	Same
Curing Method	UV Light	UV Light	Same
Product State	Liquid	Liquid	Same
Manufacturing Technology Type	Additive	Additive	Same
Volume provided	1kg/bottle	1kg bottle	Same
Shelf life	2 years	1.5 years	Similar
Standards	ISO 20795-01	ISO 20795-01	Same
Physical and Mechanical Properties	Ultimate Flexural Strength and Modulus Water Sorption and Solubility Residual Methyl Methacrylate Monomers Homogeneity Surface Characteristics Shape Capability Translucency, and Polishability Colour Freedom from Porosity	Flexural Strength and Modulus Water Sorption and Solubility Stability Residual Methyl Methacrylate Monomers Homogeneity Surface Characteristics Shape Capability, Translucency, and Polishability Freedom from Porosity Color Stability	Similar

	Color Stability Maximum stress intensity factor Total fracture work Bonding to synthetic polymer teeth		
Biocompatibility	Tested to ISO-10993-1 Genotoxicity (Part 3) Cytotoxicity(Part 5) Sensitization (Part 10) Acute Systematic Toxicity(Part 11) Subchronic toxicity(Part 11) Irritation (Part 23)	Tested to ISO7405, ISO-10993-1 Genotoxicity (Part 3) Cytotoxicity (Part 5) Acute Systematic Toxicity(Part 11) Sensitization (Part 10) Irritation (Part 10)	Similar
Additive Manufacturing	Testing, according to FDA's guidance Technical Considerations for Additive Manufactured Medical Devices, was performed and results were provided in the 510(k). These tests included evaluation of all relevant properties of the printed resin using the permitted machines. Further, tests based on considerations of the orientation during manufacturing were performed.	Testing, according to FDA's guidance Technical Considerations for Additive Manufactured Medical Devices, was performed and results were provided in the 510(k). These tests included evaluation of all relevant properties of the printed resin using the permitted machines. Further, tests based on considerations of the orientation during manufacturing were performed.	Same
PrinterDevice	RXDent-L230 3D printer	SprintRay Pro 95	Similar
Post-Cure Device	RXDent-W90(s)	SprintRay ProCure 2	Similar
Sterility	Non-sterile	Non-sterile	Same

Conclusions

The Denture Base resin is as safe and effective as its predicate device. The Denture Base has the same intended use and indication, and similar technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Denture Base and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the Denture Base is as safe and effective as the predicate device. Thus, the Denture Base is substantially equivalent.