November 10, 2022

SprintRay Inc.
Sara Moghtadernejad
Regulatory Affairs Manager
2705 Media Center Drive, Suite 100A
Los Angeles, California 90065

Re: K221678
Trade/Device Name: SprintRay High Impact Denture Base
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: October 14, 2022
Received: October 17, 2022

Dear Sara Moghtadernejad:

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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
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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

510(k) Number *(if known)*

K221678

Device Name

SprintRay High Impact Denture Base

Indications for Use *(Describe)*

The SprintRay High 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.

Type of Use *(Select one or both, as applicable)*

X 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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510(k) SUMMARY **K221678**

SprintRay High Impact Denture Base

Submitter: SprintRay Inc.
2705 Media Center Drive, Suite 100A
Los Angeles, CA 90065

Phone: +1 (800) 914-8004

Contact Person: Sara Moghtadernejad

Date Prepared: Nov 1, 2022

Name of Device: SprintRay High Impact Denture Base

Common or Usual Name: Denture Base, Prescription

Classification Name: Denture relining, repairing, or rebasing resin

Regulatory Class: Class II

Regulation Number: 21 CFR 872.3760

Product Code: EBI

Primary Predicate Device: Dentca Denture Base II (K162044)

Reference Devices: Dentca Denture Base (K143033)

Device Description

Fabrication of dental prosthetics with High Impact 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 High Impact 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.

High Impact Denture Base Resin is intended exclusively for professional dental work. SprintRay High Impact Denture Base Resin is offered in following shades/colors:

- Light Pink
- Original Pink
- Light Meharry

- Original Meharry
- Dark Meharry

High Impact 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

The SprintRay High 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.

Summary of Technological Characteristics

Light curing of a 3D printed acrylate resin is the technological principle for both the subject and predicate devices. The High Impact Denture Base is poured into a 3D printer, which relies on scanned images of the patient's oral cavity to produce a dental appliance. At a high level, the subject and predicate devices are based on the following same technological elements:

- Are a pourable acrylate resin
- Are used in conjunction with 3D printers, which rely on common 3D images to define the fabricated dental appliance
- Are cured prior to final trimming and cleaning
- Are used for the fabrication of orthodontic and dental appliances

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

- Differences in acrylate resin material

Performance Data

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

Biocompatibility Testing

The biocompatibility evaluation for High Impact Denture Base was conducted in accordance with the FDA Blue Book Memorandum #G95-1 and International Standard ISO 10993-1 and ISO 7405, as recognized by FDA. The battery of testing included the following tests:

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

High Impact Denture Base is considered tissue contacting for a period longer than 30 days (a removable prosthesis).

Bench Testing

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

- 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

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

Equivalence to Marketed Devices

Feature	Dentca Denture Base II Predicate Device	Dentca Denture Base Reference Device	SprintRay High Impact Denture Base	Conclusion
Product Code	EBI	EBI	EBI	Similar
Regulation	21 CFR 872.3760	21 CFR 872.3760	21 CFR 872.3760	Similar
Intended Use & Indications for Use	Dentca Denture Base II is a light-cured resin indicated for fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional heat-cured and auto polymerizing resins. Fabrication of dental prosthetics with Dentca Denture Base II requires a computer-aided design and manufacturing (CAD/CAM) system that includes the following components not part of the device: oral casting impression, digital denture base file created in an optical impression system, stereolithographic additive printer, and curing light equipment.	Dentca Denture Base is a light-cured resin indicated for fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional heat-cured and auto polymerizing resins. Fabrication of dental prosthetics with Dentca Denture Base requires a computer-aided design and manufacturing (CAD/CAM) system that includes the following components not part of the device: oral casting impression, digital denture base file created in an optical impression system, stereolithographic additive printer, and curing light equipment.	The SprintRay High 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.	Similar
User Population	Clinicians in dental offices	Clinicians in dental offices	Clinicians in dental offices	Similar
Chemical Description	Methacrylate-based resin	Methacrylate-based resin	Methacrylate-based resin	Similar
Material Type	Light-curable Resin	Light-curable Resin	Light-curable Resin	Similar
Curing Method	UV Light	UV Light	UV Light	Similar
Product State	Liquid	Liquid	Liquid	Similar
Manufacturing Technology Type	Additive	Additive	Additive	Similar
Volume provided	1kg bottle	1kg bottle	1kg bottle	Similar
Shelf life	>1.5 years	>1.5 years	1.5 years	Similar
Standards	ISO 20795-01	ISO 20795-01	ISO 20795-01	Similar

Physical and Mechanical Properties	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	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	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
Biocompatibility	Tested to ISO 7405, ISO-10993-1 Genotoxicity (Part 3) Cytotoxicity (Part 5) Acute Systematic Toxicity (Part 11) Sensitization (Part 10) Irritation (Part 10)	Tested to ISO 7405, ISO-10993-1 Genotoxicity (Part 3) Cytotoxicity (Part 5) Acute Systematic Toxicity (Part 11) Sensitization (Part 10) Irritation (Part 10)	Tested to ISO 7405, 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.	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.	Similar

Printer Device	SprintRay Pro 95	SprintRay Pro 95	SprintRay Pro 95	Similar
Post-Cure Device	SprintRay ProCure 2	SprintRay ProCure 2	SprintRay ProCure 2	Similar
Sterility	Non-sterile	Non-sterile	Non-sterile	Similar

Conclusions

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