October 1, 2024

SprintRay Inc.
Sara Moghtadernejad
Regulatory Affairs
2710 Media Center Drive, Suite 100A
Los Angeles, California 90065

Re: K242277
Trade/Device Name: Crown HT
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBI, EBG, ELM, PZY
Dated: August 1, 2024
Received: August 1, 2024

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 (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

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)*

K242277

Device Name

Crown HT

Indications for Use *(Describe)*

SprintRay Crown HT is a light-curable polymerizable resin intended to be used for the fabrication of; individual and fixed definitive full single crowns; definitive partial crowns in anterior and posterior area, individual and fixed single veneers; artificial teeth for dental prostheses, which are used for removable definitive full dentures; and individual and removable monolithic full and partial dentures in dental offices and laboratories. The material is an alternative to traditional restorative dental 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K242277

510(k) SUMMARY

Crown HT

Submitter: SprintRay Inc.
2710 Media Center Drive, Suite 100A
Los Angeles, CA 90065

Phone: (800) 914-8004

Contact Person: Sara Moghtadernejad

Date Prepared: August 01, 2024

Trade/Device Name: Crown HT

Common or Usual Name: Tooth Shade Resin Material

Regulation Number: 21 CFR 872.3690

Regulation Name: Tooth Shade Resin Material

Regulatory Class: Class II

Product Code: EBF

Secondar Product Code: EBI, ELM

Predicate Devices Digital Crown (K222623)

Device Description

SprintRay Crown HT is a photo-polymer methacrylate resin material used in conjunction with a 3D printer and a scanned 3D image in a dental office to build dental prosthetics by 3D printing layer upon layer of the composite material. SprintRay Crown HT resin is offered in various shades such as Bleach, A1, A2, A3, and B1. Crown HT is an alternative to traditional dental prosthesis material that is intended exclusively for professional dental work.

SprintRay Crown HT resin is intended exclusively for professional dental work. Fabrication of dental prosthetics with SprintRay Crown HT resin requires computer-aided design and CAD/CAM manufacturing system that includes the following components not part of the device: Crown HT file created in an optical impression system, 3D printer, and curing light equipment.

Crown HT resin is designed to meet appropriate ISO standards for flexibility and sorption, to withstand prolonged use in the oral cavity. It is delivered non-sterile, and instructions on curing, and cleaning the final device prior to providing it to a patient are provided in the device instruction for use (IFU) document.

Intended Use / Indications for Use

SprintRay Crown HT is a light-curable polymerizable resin intended to be used for the fabrication of; individual and fixed definitive full single crowns; definitive

partial crowns in anterior and posterior area, individual and fixed single veneers; artificial teeth for dental prostheses, which are used for removable definitive full dentures; and individual and removable monolithic full and partial dentures in dental offices and laboratories. The material is an alternative to traditional restorative dental material.

Summary of Technological Characteristics

Light-based curing of a 3D printed acrylate resin is the technological principle for both the subject and predicate devices. The Crown HT resin 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 composition

Performance Data

The subject device is considered tissue contacting for a period longer than 30 Days. The following Biocompatibility testing was performed on samples of the Crown HT resin that had been formed into dental appliances using a 3D printer in accordance with the FDA Blue Book Memorandum #G95-1 and International Standard ISO 10993-1 and ISO 7405, as recognized by FDA.

- ISO 10993-3 Genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-5 In Vitro Cytotoxicity
- ISO 10993-11 Systemic Toxicity
- ISO 10993-10 skin sensitization
- ISO 10993-23 skin irritation

Additional following bench testing based on the test steps laid out in ISO 10477 was performed using dental appliance fabricated from Crown HT resin.

- Ultimate Flexural Strength (ISO 10477)
- Water Sorption and Water Solubility (ISO 10477)
- Radio Opacity (ISO-4049)
- Print Accuracy and dimension stability Test
- Surface Finish (ISO 10477)
- Shear Bond Strength (ISO 10477)
- Translucency
- Free Monomer Extraction (ISO 20795-1)
- Tolerance
- Depth of Cure
- Viscosity
- Shade
- Material Reuse

SprintRay, Inc.'s Crown HT resin
Substantial Equivalence Chart

	Digital Crown (Predicate Device)	Crown HT (Subject Device)
Intended Use & Indications for Use	SprintRay Digital Crown is a light-curable polymerizable resin intended to be used for the fabrication of; individual and fixed definitive full single crowns; definitive partial crowns in anterior and posterior area, individual and fixed single veneers; artificial teeth for dental prostheses, which are used for removable definitive full dentures; and individual and removable monolithic full and partial dentures in dental offices and laboratories. The material is an alternative to traditional restorative dental material.	SprintRay Crown HT is a light- curable polymerizable resin intended to be used for the fabrication of; individual and fixed definitive full single crowns; definitive partial crowns in anterior and posterior area, individual and fixed single veneers; artificial teeth for dental prostheses, which are used for removable definitive full dentures; and individual and removable monolithic full and partial dentures in dental offices and laboratories. The material is an alternative to traditional restorative dental material.
User Population	Clinicians in dental offices provided permanent partial crowns and artificial teeth as indicated in the above IFU for patients.	Same
Material Type	Light-curable polymerizable resin	Same
Accessories	SprintRay Commercially available 3D printers	Same
Volume Provided	250g bottle	250g bottle or 4ml Midas Capsule
Shelf Life	1.5 years	1.5 years
Biocompatibility	Tested to ISO-10993-1, -3, -5, -10 and -11	Tested to ISO-10993-1, -3, -5, -10, -11, and 23
Performance Testing	Testing performed using methods laid out in ISO- 10477	Same
Flexural Strength (>50.0 MPa)	125-174 MPa	>124 MPa
Flexural Modulus	6116-7714MPa	>7000 MPa
Sorption (<40 µg/mm^3)	17.35 ± 2.56 µg/mm^3	11.15 ± 2.5 µg/mm^3
Solubility (<7.5 µg/mm^3)	2.16 ±1.30 µg/mm^3	0.49 ±0.59 µg/mm^3
Monomer Methyl Methacrylate (<2.2S%)	Not detectable	Not detectable

In all instances, the Crown HT resin functioned as intended and the outcomes were as expected.

Conclusions

The Crown HT resin is as safe and effective as its predicate device. The Crown HT resin 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 Crown HT resin and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the Crown HT resin is as safe and effective as the predicate device. Thus, the Crown HT resin is substantially equivalent.