December 14, 2022

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

Re: K222623
Trade/Device Name: Digital Crown
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBI, ELM
Dated: September 15, 2022
Received: September 15, 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
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

510(k) Number *(if known)*

K222623

Device Name

Digital Crown

Indications for Use *(Describe)*

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.

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

Digital Crown

K222623

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

Phone: +1 (800) 914-8004

Contact Person: Sara Moghtadernejad

Date Prepared: November 22, 2022

Name of Device:	Digital Crown (K222623)
Common or Usual Name:	Tooth Shade Resin Material
Classification Name:	Tooth Shade Resin Material
Regulatory Class:	Class II
Regulation Number:	21 CFR 872.3690
Product Code:	EBF
Secondary Product Codes:	EBI, ELM
Predicate Device:	E-Dent 1000 (K210977) (Primary Predicate)

Device Description

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

Fabrication of dental prosthetics with SprintRay Digital Crown resin requires computer-aided design and CAD/CAM manufacturing system that includes the following components not part of the device: oral casting impression, digital crown file created in an optical impression system, 3D printer, and curing light equipment. SprintRay Digital Crown Resin is intended exclusively for professional dental work. Digital Crown Resin is offered in following shades/colors: Bleach, A1, B1.

The device is manufactured via additive manufacturing process using a 3D printer with 405 nm wavelength, 50µm print layer thickness, and light energy of 28.8 mW/cm^2.

Digital Crown 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 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

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.

Summary of Technological Characteristics

Light-based curing of a 3D printed acrylate resin is the technological principle for both the subject and predicate devices. Digital Crown 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 following performance data were provided in support of the substantial equivalence determination.

<u>Biocompatibility Testing</u>
The biocompatibility evaluation for Digital Crown 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

Digital Crown is considered tissue contacting for a period longer than 30 days.

Bench Testing

Additional bench testing based on the test steps laid out in ISO 10477 and ISO 4049 was performed using dental appliance fabricated from Digital Crown resin.

- Flexural Strength and Modulus
- Water Sorption and Solubility
- Radio-opacity
- Print Accuracy and Dimensional Stability
- Shape Capability, Translucency, and Polishability
- Freedom from Porosity
- Color Stability and Shade Consistency
- Residual Methyl Methacrylate Monomers
- Stability

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

Equivalence to Marketed Devices

Feature	EnvisionTEC's E-Dent 1000	SprintRay Digital Crown	Conclusion
Product Code	EBF EBI ELM	EBF EBI ELM	Similar
Regulation	21 CFR 872.3690 21 CFR 872.3760 21 CFR 872.3590	21 CFR 872.3690 21 CFR 872.3760 21 CFR 872.3590	Similar
Intended Use & Indications for Use	E-Dent 1000 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, individual and fixed single veneers, artificial teeth for dental prostheses, which are used for removable permanent full dentures, individual and removable monolithic full and partial dentures in dental laboratories. The material is an alternative to traditional restorative dental material. E-Dent 1000 is intended	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	Similar

	exclusively for professional dental work. Fabrication of dental applications with E-Dent 1000 requires a computer aided and manufacturing (CAD/CAM) system that includes the following components: digital dental files based on a digital impression, or in case of artificial teeth for dental prostheses the digital dental files based on manufacturer's data, a digital light processing (DLP) printer, and curing light equipment.	alternative to traditional restorative dental material.	
User Population	Clinicians in dental offices	Clinicians in dental offices	Similar
Chemical Description	Methacrylate-based resin	Methacrylate-based resin	Similar
Material Type	Light-curable Resin	Light-curable Resin	Similar
Curing Method	UV Light	UV Light	Similar
Product State	Liquid	Liquid	Similar
Manufacturing Technology Type	Additive	Additive	Similar
Volume provided	1kg bottle	1kg bottle	Similar
Shelf life	>1.5 years	1.5 years	Similar
Standards	ISO 10477 ISO 4049	ISO 10477 ISO 4049	Similar
Physical and Mechanical Properties	Translucency Dimensional stability Color and color stability Flexural Strength and Modulus Freedom from Porosity Water Sorption and Solubility Stability	Shape Capability, Translucency, and Polishability, Radio-opacity Print Accuracy and Dimensional Stability Color Stability and Shade Consistency Flexural Strength and Modulus Freedom from Porosity Water Sorption and Solubility Stability	Similar

		Residual Methyl Methacrylate Monomers	
Biocompatibility	Tested to ISO 7405, ISO-10993-1 Cytotoxicity (Part 5) Acute Systematic Toxicity (Part 11) Sensitization (Part 10) Irritation (Part 10)	Tested to ISO 7405, ISO-10993-1 Cytotoxicity (Part 5) Acute Systematic Toxicity (Part 11) Sensitization (Part 10) Irritation (Part 10) Genotoxicity (Part 3)	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.	Similar
Sterility	Non-sterile	Non-sterile	Similar

Conclusions

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