November 26, 2024

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

Re: K242559
Trade/Device Name: Digital Temp
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: August 27, 2024
Received: August 28, 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
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242559

Device Name

Digital Temp

Indications for Use *(Describe)*

SprintRay Digital Temp is a light-curable resin indicated for the fabrication of individual and fixed temporary full single crowns, temporary partial crowns, and temporary bridges. 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.

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510(k) SUMMARY **K242559**

SprintRay's Digital Temp

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

Phone: (800) 914-8004

Contact Person: Sara Moghtadernejad

Date Prepared: August 27, 2024

Trade/Device Name:	Digital Temp
Regulation Number:	21 CFR 872.3770
Regulation Name:	Temporary crown and bridge resin
Regulatory Class:	Class II
Product Code:	EBG
Primary Predicate Device:	E-Temp (K211101)

Device Description

SprintRay Digital Temp 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 Digital Temp resin is offered in various shades such as Bleach, A1, A2 and B1. Digital Temp is an alternative to traditional dental prosthesis material that is intended exclusively for professional dental work.

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

Digital Temp 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 indication for use document.

Intended Use / Indications for Use

SprintRay Digital Temp is a light-curable resin indicated for the fabrication of individual and fixed temporary full single crowns, temporary partial crowns, and temporary bridges. 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 Digital Temp 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

Biocompatibility testing was performed on samples of the Digital Temp resin that had been formed into dental appliances using a 3D printer.

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

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

Conclusions

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