April 15, 2026

Sprintray, Inc.
Sara Moghtadernejad
Global Director of RA/QA
2710 Media Center Dr., Suite #100a
Los Angeles, California 90065

Re: K260661
Trade/Device Name: Midas Restore
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, ELM
Dated: February 27, 2026
Received: March 2, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260661

Device Name
Midas Restore

Indications for Use *(Describe)*
Midas Restore is a light-curable polymerizable resin intended to be used for the fabrication of individual and fixed definitive full single crowns; definitive partial crowns (e.g., inlays, onlays) in anterior and posterior area, individual and fixed single veneers; artificial teeth for dental prostheses, which are used for removable definitive full 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.

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510(k) SUMMARY

SprintRay's Midas Restore

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

Phone: (800) 914-8004

Contact Person: Dr. Sara Moghtadernejad

Date Prepared: February 27, 2026

Trade/Device Name: Midas Restore

Regulation Number: 21 CFR 872.3690

Regulation Name: Tooth Shade Resin Material

Common Name: Material, tooth shade, resin

Regulatory Class: Class II

Product Code: EBF

Secondar Product Code: ELM

Predicate Devices Digital Crown (K222623)

Device Description

SprintRay Midas Restore 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 Midas Restore is offered in various shades such as Bleach, A1, A2, A3, B1, C2, and unpigmented, compatible with the VITA classical A1- D4 shade guide for color matching. Midas Restore is an alternative to traditional dental prosthesis material that is intended exclusively for professional dental work.

SprintRay Midas Restore resin is intended exclusively for professional dental work. Fabrication of dental prosthetics with SprintRay Midas Restore resin requires computer-aided design and CAD/CAM manufacturing system that

includes the following components not part of the device: Midas Restore file created in an optical impression system, 3D printer, and curing light equipment.

Midas Restore 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

Midas Restore is a light-curable polymerizable resin intended to be used for the fabrication of individual and fixed definitive full single crowns; definitive partial crowns (e.g., inlays, onlays) in anterior and posterior area, individual and fixed single veneers; artificial teeth for dental prostheses, which are used for removable definitive full 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 Midas Restore resin used with the Midas 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 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

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 Midas Restore 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 Midas Restore resin.

- Ultimate Flexural Strength (ISO 10477)
- Water Sorption and Water Solubility (ISO 10477)
- Radio Opacity (ISO 4049)
- Print Accuracy and Dimension Stability
- Surface Finish (ISO 10477)
- Shear Bond Strength (ISO 10477)
- Free Monomer Extraction (ISO 20795-1)
- Tolerance
- Depth of Cure
- Viscosity
- Shade and Color Stability
- Hardware/Software Validation Testing

Conclusions

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

SPRINTRAY, INC.'S
MIDAS RESTORE RESIN
SUBSTANTIAL EQUIVALENCE CHART

	Digital Crown (Predicate Device)	Midas Restore (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.	Midas Restore is a light-curable polymerizable resin intended to be used for the fabrication of individual and fixed definitive full single crowns; definitive partial crowns (e.g., inlays, onlays) in anterior and posterior area, individual and fixed single veneers; artificial teeth for dental prostheses, which are used for removable definitive full 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	SprintRay Midas 3D printer
Volume Provided	250g bottle	4ml Midas Capsule
Shelf Life	1.5 years	2 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	120-150 MPa
Sorption (<40 µg/mm^3)	17.35 ± 2.56 µg/mm^3	22-24 µg/mm^3
Solubility (<7.5 µg/mm^3)	2.16 ±1.30 µg/mm^3	1.0-2.5 µg/mm^3
Monomer Methyl Methacrylate (<2.2S%)	Not detectable	Not detectable

Radio Opacity per ISO 10477	Equivalent to aluminum	Equivalent to aluminum
Shear Bond Strength ISO 10477	PASS	PASS
Shade and Color Stability after Irradiation and Water Sorption	Shade does not change, PASS	Shade does not change, PASS
Surface Finish	Polishable	Polishable
Hardware/Software Validation Testing	Validated with SprintRay Workflow	Validated with SprintRay workflow
Accuracy Fitting	PASS using recommended SprintRay Workflow	PASS using recommended SprintRay Workflow
Depth of Cure	Between 100 to 300 microns at the 100 microns print layer time	Between 100 to 300 microns at the 100 microns print layer time
Shade	Pass per VITA shade guide	Pass per VITA shade guide