June 18, 2026

GC America, Inc.
Futoshi Fusejima
Director of PE & Regulatory Affairs
3737 W. 127th St.
Alsip, Illinois 60803

Re: K261246
Trade/Device Name: SRGC-06
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: April 15, 2026
Received: April 16, 2026

Dear Futoshi Fusejima:

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,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261246

Please provide the device trade name(s).

SRGC-06

Please provide your Indications for Use below.

INDICATIONS FOR USE
•Individual and fixed definitive full single crowns.
•Definitive partial crowns in anterior and posterior area.
•Individual and fixed single veneers.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [ ] Adults (22 years old and greater)

K261246

510(k) Summary
SRGC-06

Submitter: GC America Inc.
3737 W. 127th Street
Alsip, IL 60803

Phone: (708)926-3050

Contact Person: Futoshi Fusejima

Date Prepared: April 8, 2026

Trade/Device Name	SRGC-06
Device Classification Name	Material, Tooth Shade, Resin
Common or Usual Name	Tooth Shade Resin Material
Regulatory Class	Class II
Product Code	EBF
Regulation Number	21 CFR 872.3690

Predicate Devices:

	Product	**Applicant**	**510(k) No.**	**Code No.**	**Decision Date**
Predicate Device	Crown HT	SprintRay, Inc.	K242277	EBF, EBG, EBI, ELM, PZY	10/01/2024
Reference Device	HTFX-222	GC America, Inc.	K133182	EBF	04/09/2014

Device Description:
SRGC-06 is an alternative to traditional dental prosthesis material that is intended exclusively for professional dental work. The device is conjunction with a SprintRay MIDAS 3D printer. It is available in the following shades: U, A3, AO2. The compressive strength is 370 MPa. The flexural strength is 170 MPa. The biaxial strength is 220 MPa. The material has a radiopacity equivalent to 2.5-3.0 mm of aluminium (dentin = 1 mm, enamel = 2 mm). The particle size of inorganic fillers range is 0.02-1.3 µm. After printing and post-curing, the material is intended for fabrication of:

- Individual and fixed definitive full single crowns
- Definitive partial crowns in anterior and posterior area

- Individual and fixed single veneers

For professional use only.

Indications for Use:

- Individual and fixed definitive full single crowns
- Definitive partial crowns in anterior and posterior area
- Individual and fixed single veneers

Summary of Technological Characteristics:
SRGC-06 is a 3D-printer resin material in which glass filler particles are dispersed in a cross-linked polymeric matrix and chemically bonded to the resin network. The product contains a photo initiator that enables light-induced curing/polymerization, resulting in a conversion from a paste to a hard, solid material.

Applicant device and predicate devices are substantially equivalent in the following points.

- Light-curable polymerizable resin
- Intended Use and Indications for Use; that is to fabricate prosthetic restorations (crowns, inlays, and veneers)
- Provided in the same 4 mL capsule
- Method of use because both are operated with the MIDAS 3D Printer manufactured by Sprintray.
- Performance evaluation

The following difference may be noted between applicant device and predicate device.

- The substances used in the applicant device differ from those used in the predicate device.
- The Indication for Use of the applicant device is not identical to that of the predicate device with respect to the fabrication of artificial teeth.

Although the chemical composition is not identical, both the applicant and predicate device contain methacrylate based monomers, photo initiators, inorganic fillers, and pigments, which are commonly used in dental 3D printing resin materials; therefore, the two devices are considered comparable in material characteristics. The applicant device does not introduce any new indications, as all intended uses of the applicant device are included within the predicate device Crown HT.
In conclusion, the applicant device is substantially equivalent to the predicate device in technological principle.

Performance Data:
The biological safety of this product was evaluated in accordance with ISO 10993-1:2018 , Use of International Standard ISO10993-1, "Biological evaluation of medical devices - Part

1: Evaluation and testing within a risk management process" and ISO 7405:2025 and following the flowchart in “ISO 10993-1:2018 Figure 1 - Summary of the systematic approach to a biological evaluation of medical devices as part of a risk management process".
In accordance with ISO 10993-1:2018 “Annex A Endpoints to be addressed in a biological risk assessment”, the following are contact and contact duration of this product with the body.

Category : Externally communicating medical device
Contact : Tissue/bone/dentin
Contact duration : Long term (> 30 d)

- ISO 10993-5 In Vitro Cytotoxicity
- ISO 10993-10 Skin Sensitization
- ISO 10993-23 Skin Irritation

Additional bench testing based on the test steps laid out in ISO 10477, ISO 4049, the FDA guidance documents entitled “Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions - Guidance for Industry and FDA Staff” and FDA Guidance for Industry titled “Technical Considerations for Additive Manufactured Medical Devices December 2017”, ISO 9917-1, American Dental Association (ADA) specification No. 27-1993 Resin-Based Filling Materials, and ISO 6872 were performed using dental appliance fabricated from SRGC-06.

- Flexural strength (ISO 10477)
- Water sorption and Solubility (ISO 10477)
- Radio-opacity (ISO 4049)
- Surface finish (ISO 10477)
- Bond strength (ISO 10477)
- Print Accuracy & Dimensional Stability
- Printer compatibility
- Tolerance (fit accuracy testing)
- Depth of Cure
- Translucency
- Compressive strength (ISO 9917-1)
- Elastic modulus (ADA specification No. 27-1993)
- Surface hardness (ISO 10477
- Filler particle size distribution
- Biaxial strength (ISO 6872)

SRGC-06
Substantial Equivalence Chart

	Applicant device	Predicate device	Reference device	Rational
Trade name	**SRGC-06**	**Crown HT** K242277	**HTFX-222** K133182	
Manufacturer	GC Corporation	SprintRay inc.	GC Corporation	
Product category	EBF	EBF, EBG, EBI, ELM, PZY	EBF	The applicant device is identical to both the predicate device and the reference device.
Indications for Use	1. Individual and fixed definitive full single crowns 2. Definitive partial crowns in anterior and posterior area 3. Individual and fixed single veneers	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 prosthesis, 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 and restorative dental material.	HTFX-22 is a light-cured, nano-filled, radiopaque composite resin filled in a syringe. The device is a universal type. The material is available in 8 shades. - The device is non-sterile when used, and therefore, sterilization and disinfection is not needed for the proposed device. - Applicant device does not contain software/firmware. - Applicant device does not require EMC and Electrical Safety evaluation. - Applicant device is not an in vitro diagnostic device (IVD). Indications for Use: 1. Liner or base 2. Blocking out undercuts 3. Repair of direct and indirect aesthetic restorations: composites, veneers, crowns, and	Applicant device is equivalent to predicate device except for the fabrication of artificial teeth, which applicant device does not claim as an intended use.

			bridges (including temporary crowns and bridges), defect margins when margins are in enamel. 4. Sealing hypersensitive areas 5. Fixture sealant 6. Direct restorative form small Class I, II, III, IV, and V cavities	
Product description	SRGC-06 is an alternative to traditional dental prosthesis material that is intended exclusively for professional dental work. The device is conjunction with a SprintRay MIDAS 3D printer. It is available in the following shades: U, A3, AO2.	Crown HT is an alternative to traditional dental prosthesis material that is intended exclusively for professional dental work. The device is manufactured via additive manufacturing process using a DLP 3D printer, and 100-µm print layer thickness. It is available in the following shades: Bleach, A1, A2, A3, unpigmented, and B1. Crown HT is an alternative to traditional dental prosthesis material that is intended exclusively for professional dental work.	HTFX-222 is a light-cured, radio-opaque, flowable restorative material to be used intra-orally and classified as a Type 1 and Class 2 (Groupe 1) per ISO standard 4049. This material has a radiopacity equivalent to 3.0 - 3.5 mm of aluminum (dentine = 1 mm, enamel = 2 mm). The particle size of inorganic fillers range is 0.02 - 1.3 µm. The total amount of inorganic filler is approximately 46 vol%.	Applicant device is equivalent to predicate device.
Material Type	Light-curable polymerizable resin	Light-curable polymerizable resin	N/A	Applicant device is equivalent to predicate device.

Delivery form	Paste in 4ml Midas capsule	Paste in 250g bottle or 4ml Midas Capsule	Paste in a syringe	Applicant device is equivalent to predicate device.
Chemical composition	Barium glass, dimethacrylate, initiator, pigment, silicon dioxide, stabilizer	Ceramic powder, modified polyester resin, monomeric methacrylate, dimethacrylate oligomer, photoinitiator, proprietary ingredients	Barium glass, dimethacrylate, initiator, pigment, silicon dioxide, stabilizer	Applicant device and reference device are the same. The applicant device and Predicate Device are considered equivalent because the methacrylate components are polymerized by a photo-initiator.
Curing mode	Light-curing	Light-curing	Light-curing	The applicant device is the same as predicate device and reference device.
Sterilization	No sterilization	No sterilization	No sterilization	The applicant device is the same as predicate device and reference device.
Storage temperature	4 – 25℃	15 – 25℃	4 – 25℃	The applicant device is the same as reference device.
Shelf-Life	2 years	1.5 years	3 years	The shelf-life of applicant device is longer than that of predicate device, while it is adequately supported.
Available shades	U, A3, AO2	Bleach, A1, A2, A3, B1, Unpigmented	A1, A2, A3, A3.5, A4, AO2, AO3, CV	The applicant device shades A3 and AO2 are equivalent to the predicate device shade A3 and the reference device shades A3 and AO2. The applicant device shade U is a universal shade and corresponds to shade A2 of

				the predicate and reference devices.
Direction for use	REPARATION DESIGN PRINTING CLEANING OF THE PRINTED OBJECTS POST CURING FINISHING AND POLISHING CEMENTATION ADDITIONAL APPLICATION AND REPAIR CHARACTERIZATION	Designing Capsule Priming 3D Printing Part and Support Removal Washing and Drying Post Curing Finishing Characterization (optional) Bonding	1. Preparations 2. Shade Selection 3. Cavity Preparation 4. Bonding Treatment 5. Placement of HTFX-222 6. LIGHT CURING 7. Finishing and Polishing	Applicant device and predicate device share the same method of use differs only in print profile.
User Population	Clinicians in dental offices provided permanent partial crowns and artificial teeth as indicated in the IFU for patients.	Clinicians in dental offices provided permanent partial crowns and artificial teeth as indicated in the IFU for patients.	N/A	Applicant device is equivalent to predicate device.
Accessories	SprintRay Commercially available 3D printers (MIDAS 3D Printer)	SprintRay Commercially available 3D printers	N/A	Applicant device is equivalent to predicate device.
Biocompatibility	Tested to ISO-10993-1 and ISO 7405	Tested to ISO 10993-1	Tested to ISO-10993-1	
Performance Testing	Testing performed using methods laid out in ISO-10477 and ISO 4049	Testing performed using methods laid out in ISO-10477	Testing performed using ISO 4049	
Flexural strength (≥50 MPa)	183 MPa	135 MPa	N/A	Applicant device is substantially equivalent to predicate device.
Solubility (≤7.5 µg/mm^3)	0 µg/mm^3	0 µg/mm^3	N/A	Applicant device is substantially equivalent to predicate device.
Water sorption (≤40 µg/mm$^{3)}$	12.6 µg/mm^3	7.8 µg/mm^3	N/A	Applicant device is substantially equivalent to predicate device.

Radio-opacity (Equal to or greater than the same thickness of aluminum)	Passed	Passed	N/A	Applicant device is substantially equivalent to predicate device.
Surface finish (It is confirmed to be glossy by visual inspection)	Passed	Passed	N/A	Applicant device is substantially equivalent to predicate device.
Bond strength (≥5 MPa)	14.6 MPa	10.2 MPa	N/A	Applicant device is substantially equivalent to predicate device.
Translucency Evaluation (≥ 10%)	23% (A3)	24% (A3)	N/A	Applicant device is substantially equivalent to predicate device.
Depth of Cure (250-600 µm)	316 µm	377 µm	N/A	Applicant device is substantially equivalent to predicate device.
Compressive strength (100 MPa or more)	379 MPa	255 MPa	N/A	Applicant device is substantially equivalent to predicate device.
Elastic modulus	7.9 GPa	7.7 GPa	N/A	Applicant device is substantially equivalent to predicate device.
Surface hardness	74.3 HV0.2	53.7 HV0.2	N/A	Applicant device is substantially equivalent to predicate device.
Filler particle size distribution	0.02－1.3 mm	N.D.	0.02－1.3 mm	Applicant device is substantially equivalent to reference device.
Biaxial strength (100 MPa or more)	229 MPa	151 MPa	N/A	Applicant device is substantially equivalent to predicate device.

In all instances, the SRGC-06 resin functioned as intended, and the outcomes were as expected.

Conclusions:
Based on similarities in indications for use, technology, safety and effectiveness, the applicant device is substantially equivalent to the predicate devices.