April 29, 2025

SprintRay Inc.
Sara Moghtadernejad
Global Dircetor of Regulatory Affairs and Quality Assurance
2710 Media Center Drive, Suite #100A
Los Angeles, California 90065

Re: K250617
Trade/Device Name: Apex Flex
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: February 28, 2025
Received: February 28, 2025

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)*

K250617

Device Name

Apex Flex

Indications for Use *(Describe)*

SprintRay Apex Flex is an alternative to traditional thermoplastic material used for the fabrication and repair of partial dentures. It is intended exclusively for professional dental work.

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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"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."

K250617

510(k) SUMMARY

SprintRay's Apex Flex

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

Phone: (800) 914-8004

Contact Person: Dr. Sara Moghtadernejad

Date Prepared: March 14, 2025

Trade/Device Name: Apex Flex
Regulation Number: 21 CFR 872.3760
Regulation Name: Resin, Denture, Relining, Repairing, Rebasing
Common Name: Resin, Denture, Relining, Repairing, Rebasing
Regulatory Class: Class II
Product Code: EBI
Primary Predicate Device: iFlex-Star V (K072402)
Secondary Predicate Device: TCS® Unbreakable (K053060)
Reference Device: Night Guard Flex (K212448)

Device Description

SprintRay Apex Flex is a photo-polymeric methacrylate/acrylate resin material used in conjunction with a 3D printer and a scanned 3D image in a dental office to fabricate partial dentures by 3D printing layer upon layer of the composite material. The product is available in two shades: Light Pink and Standard Pink.

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

Apex Flex 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 Apex Flex is an alternative to traditional thermoplastic material used for the fabrication and repair of partial dentures. It is intended exclusively for professional dental work.

Summary of Technological Characteristics

The subject device is a light-curable acrylate resin formulated for the fabrication of flexible partial dentures via 3D printing. The predicate devices, are thermoplastic nylon material designed for flexible partial dentures, manufactured using injection molding techniques. While the manufacturing process differs (additive 3D printing for the subject device versus injection molding for the predicate) and the base material differs (acrylate-based resin for the subject device versus nylon for the predicate device), the intended use (flexible partial denture) is similar. The finished subject device exhibits technological characteristics comparable to that of the predicate devices. The subject device and predicate devices share the identical indication for use: providing a removable, flexible-based partial denture that supports artificial teeth to restore masticatory function and improve aesthetics. While the subject device is manufactured via 3D printing and the predicate devices are injection-molded, this difference in manufacturing technology does not alter the device's intended use or principle of operation *in vivo*. Clinical success for aforementioned devices depends on accurate impressions/scans, proper design, and fitting. Patients experience the same functional outcome regardless of the manufacturing method. A 3D-printed reference device is included to further demonstrate manufacturing technology equivalency. Therefore, the subject device is substantially equivalent to the predicate devices in its principle of operation and reference device to the method of manufacturing.

SUBSTANTIAL EQUIVALENCE CHART

	Flex-Star V (Predicate Device)	**TCS Unbreakable (Secondary Predicate)**	**SprintRay NightGuard Flex (Reference Device)**	**Apex Flex (Subject Device)**
Intended Use & Indications for Use	CMP's Flex-Star V is used for the fabrication of partial or full removable dentures, as well as occlusal splints and night guards. It is to be used only by professional dental practitioners who make or repair dentures for patients.	TCS® Unbreakable is a break resistant material used in the fabrication and repair of base plates for removeable dental prosthetic appliances where superior flexibility and patient comfort for the lifetime of the prosthetic are significant concerns. This includes, but not to be limited to, full and partial dentures, orthodontic devices,	The NightGuard Flex is intended to be used for the manufacture of orthodontic and dental appliances in a clinical setting by trained dental professionals. The NightGuard Flex is indicated for use in the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints and repositioners.	SprintRay Apex Flex is an alternative to traditional thermoplastic material used for the fabrication and repair of partial dentures. It is intended exclusively for professional dental work.

		occlusal splints, and night guards.		
User Population	Dental professionals (dentists, prosthodontists, dental laboratory technicians) who fabricate dental appliances.	Dental professionals (dentists, prosthodontists, dental laboratory technicians) who fabricate dental appliances.	Dental professionals (dentists, prosthodontists, dental laboratory technicians) who fabricate dental appliances	Same
Material Type	Thermoplastic nylon resin (for injection molding)	Thermoplastic nylon resin (for injection molding)	Light-curable polymerizable resin	Light-curable polymerizable resin
Accessories	Injection molding equipment (injector, flasks, etc.), polishing tools, finishing burs.	Injection molding equipment (injector, flasks, etc.), polishing tools, finishing burs.	SprintRay Commercially available 3D printers	SprintRay Commercially available 3D printers
Volume Provided	Typically provided in pre-dosed cartridges or pellets (e.g., 25g, 50g per cartridge/pellet).	Typically provided in pre-dosed cartridges or pellets (e.g., 25g, 50g per cartridge/pellet).	1000g-bottle	500g-bottle
Shelf Life	Typically, 1-3 years, stored in a cool, dry place away from direct sunlight.	Typically, 1-3 years, stored in a cool, dry place away from direct sunlight.	1.5 years	1.5 years
Biocompatibility	Tested to ISO-10993-1	Tested to ISO-10993-1	Tested to ISO-10993-1 and ISO 7405	Tested to ISO-10993-1 and ISO 7405
Performance Testing	Testing performed using methods laid out in ISO 20795-1	Testing performed using methods laid out in ISO 20795-1	Testing performed using methods laid out in ISO 20795-2	Testing performed using methods laid out in ISO 20795-1
Flexural Strength	26.9 ± 0.7 MPa*	Similar	10.4 - 11.2 MPa	26.5 ± 0.8 MPa
Flexural Modulus	612 ± 17 MPa*	353 ± 4.2 MPa	169 ± 1.6 MPa	748 ± 21 MPa
Sorption	Pass	14.8 ± 0.4 $\mu g/mm^3$	19.5 ± 1.6 $\mu g/mm^3$	8.9 ± 0.3 $\mu g/mm^3$
Solubility	Pass	2.5 ± 0.7 $\mu g/mm^3$	1.6 ± 0.7 $\mu g/mm^3$	3.3 ± 0.2 $\mu g/mm^3$
Monomer Methyl Methacrylate (<2.2 %)	Not detectable	Not detectable	Not detectable	Not detectable

*__Source:__ Lee, Hae-Hyoung, Jung-Hwan Lee, Tae-Hyun Yang, Yu-Jin Kim, Si-Chul Kim, Gyu-Ri Kim, Hyung-Rae Kim, Chung-Jae Lee, and Chikahiro Okubo. "Evaluation of the flexural mechanical properties of various thermoplastic denture base polymers." *Dental materials journal* 37, no. 6 (2018): 950-956.

Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for Apex Flex 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

Apex Flex is considered tissue contacting for a period longer than 30 days (a removable prosthesis).

Bench Testing

Apex Flex was tested for conformity with the industry consensus standard ISO 20795-1. The battery of testing included the following tests:

- Flexural Strength
- Flexural Modulus
- Total Fracture Work
- Maximum Stress Intensity Factor
- Water Sorption
- Water Solubility
- Residual Monomer
- Tolerance
- Depth of Cure
- Accuracy Fitting
- Shade
- Freedom from Porosity
- Homogeneity
- Viscosity

In all instances, Apex Flex functioned as intended and the outcomes were as expected.

Conclusions

The Apex Flex resin is as safe and effective as its predicate devices. The Apex Flex resin has the same intended use and indication, and similar technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Apex Flex resin and its predicate devices

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