July 14, 2023

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

Re: K230445
Trade/Device Name: OnX Tough
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI, PZY
Dated: May 18, 2023
Received: May 19, 2023

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,

FDA Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., 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)*

K230445

Device Name

OnX Tough

Indications for Use *(Describe)*

SprintRay OnX Tough is a tooth shade ceramic-hybrid resin used for the fabrication of hybrid denture prosthetics, implant-supported denture prosthetics, monolithic full and partial removable dentures, and preformed denture teeth to be used in a denture.

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

OnX Tough

K230445

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

Phone: (800) 914-8004

Contact Person: Sara Moghtadernejad

Date Prepared: July 12, 2023

Name of Device:	OnX Tough	
Common or Usual Name	Denture, Prescription	
Regulation Number and Names: **Product Codes** **Device Class**	21 CFR 872.3760, Denture Relining, Repairing, or Rebasing Resin EBI II	21 CFR 872.3590, Additively Manufactured, Preformed, Resin Denture Tooth PZY II 510(k)-Exempt
Primary Predicate	K221678, SprintRay High Impact Denture Base, (EBI product code)	
Secondary Predicate	K151142, IvoBase CAD for Zenotec, (EBI product code)	

Device Description

OnX Tough 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 OnX Tough resin requires computer-aided design and CAD/CAM manufacturing system that includes the following components not part of the device: oral casting impression, digital denture file created in an optical impression system, 3D printer, and curing light equipment.

The material is an alternative to traditional dental prostheses material. OnX Tough resin is intended exclusively for professional dental work.

OnX Tough 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 OnX Tough is a tooth shade ceramic-hybrid resin used for the fabrication of hybrid denture prosthetics, implant-supported denture prosthetics, monolithic full and partial removable dentures, and preformed denture teeth to be used in a denture.

The intended use of fabrication of monolithic full and partial removable dentures is the same as the primary predicate device (K221678) (product code EBI). The fabrication of hybrid denture prosthetics, implant-supported denture prosthetics is the same as the secondary predicate device (K151142) (product code EBI). The fabrication of preformed denture teeth to be used in a denture is Class II, but 510(k)-exempt (product code PZY), therefore no predicate is necessary.

The intended use, technological characteristics, and critical specifications, of OnX Tough are similar to both predicate devices.

Summary of Technological Characteristics

OnX Tough and the primary predicate device (K221678) are both 3D printed denture devices. The liquid resin is polymerized in the 3D printer, which creates the final denture device. The secondary predicate device (K151142) is a pre-polymerized denture disk that is milled to the final shape of the impression. Here is a more detailed explanation of the two processes:

<u>OnX Tough and Primary Predicate Device</u>

1. An impression of the patient's mouth is taken.
2. The impression is scanned and sent to a 3D printer.
3. The 3D printer creates a mold of the denture.
4. The mold is filled with liquid resin.
5. The resin is polymerized, which creates the final denture device.

<u>Secondary Predicate Device</u>

1. An impression of the patient's mouth is taken.
2. The impression is scanned and sent to a computer.
3. A pre-polymerized denture disk is created on the computer.
4. The disk is milled to the final shape of the impression.
5. The milled disk is placed in the patient's mouth.

Both OnX Tough and the primary predicate device are created using 3D printing technology. This technology allows for the creation of custom-fit dentures that are more comfortable and durable than traditional dentures. The secondary predicate device is a less expensive option that is still effective in providing patients with a new set of teeth. The principles of operation are essentially similar; therefore, the OnX Tough is substantially equivalent to its predicate devices.

The following technological differences exist between the subject and predicate devices:

- Differences in acrylate resin material.

Performance Data

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

Biocompatibility Testing

The biocompatibility evaluation for OnX Tough 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

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

Bench Testing

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

- Flexural Strength and Modulus
- Water Sorption and Solubility
- Stability
- Residual Methyl Methacrylate Monomers
- Homogeneity
- Surface Characteristics
- Shape Capability, Translucency, and Polishability
- Freedom from Porosity
- Color Stability

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 also performed.

In all instances, OnX Tough functioned as intended and the outcomes were as expected.

EQUIVALENCE TO MARKETED DEVICES

	Testing Standards	**High Impact Denture Base (Primary Predicate)**	**IvoBase CAD for Zenotec (Secondary Predicate)**	**OnX Tough (Subject Device)**
Intended Use & Indications for Use	N/A	The SprintRay High Impact Denture Base resin is a light curable polymerizable resin intended to be used for the fabrication and repair, of full and partial removable dentures and baseplates. The material is an alternative to traditional denture base material.	IvoBase CAD for Zenotec, IvoBase CAD Bond and Modelling Liquid is a system used: For the fabrication of removable dentures e.g.: partial and complete denture prosthetics, hybrid denture prosthetics, combined denture prosthetics, mouthguards, implant-supported denture prosthetics	SprintRay OnX Tough is a tooth shade ceramic-hybrid resin used for the fabrication of hybrid denture prosthetics, implant-supported denture prosthetics, monolithic full and partial removable dentures, and preformed denture teeth to be used in a denture.
User Population	N/A	Clinicians in dental offices	Clinicians in dental offices	Clinicians in dental offices
Biocompatibility	ISO- 10993-1, -3, -5 -10 and -11	Passed	Passed	Passed
Composition	N/A	Methacrylate Monomer/oligomer s that polymerized to Methymethacylate Based polymer	Traditional PMMA Polymer/monomer denture base material with pigmentation for shade.	Methacrylate Monomer/oligomers that polymerized to Methymethacylate Based polymer. The subject device has similar polymer family to the predicates except for small changes in pigments.

Principles of operation	N/A	Additive manufacturing of the polymerized denture to the final shape of the impression.	Polymerized denture disk milled to the final shape of the impression.	Additive manufacturing of the polymerized denture to the final shape of the impression.
Performance Testing		Testing performed according to ISO standards	Testing performed according to ISO standards	Testing performed according to ISO standards

Flexural Strength (≥65 MPa)	ISO 20795-1	74.69 ± 1.55 MPa	≥65 MPa	71.03 ± 1.45 MPa
Flexural Modulus (≥2000 MPa)	ISO 20795-1	2253 ± 78 MPa	≥2000 MPa	2271 ± 118 MPa
Sorption (≤32 µg/mm^3)	ISO 20795-2	28 ± 1 µg/mm^3	≤32 µg/mm^3	31 ± 1 µg/mm^3
Solubility (≤5 µg/mm^3)	ISO 20795-2	3.5 ± 0.5 µg/mm^3	≤5 µg/mm^3	4.0 ± 0.5 µg/mm^3
Monomer Methyl Methacrylate (≤2.2%)	ISO 20795-1	Pass	Pass	Pass
K_{max} ≥1.9 MPa*m$^{1/2}$	ISO 20795-1	3.328 ± 0.147	2.5	3.176 ± 0.209
Total fracture work, ≥900 J/m^2	ISO 20795-1	1232 ± 119	1172	945 ± 88

Conclusions

The OnX Tough resin is as safe and effective as its predicate devices. The OnX Tough has the same intended use and indication, and similar technological characteristics as its predicate devices. The minor technological differences between the OnX Tough and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the OnX Tough is as safe and effective as the predicate devices. Thus, the OnX Tough is substantially equivalent.