June 20, 2024

Belport Company, Inc., Gingi-Pak
Daniel Gallegos
Regulatory Affairs Specialist
670 Endeavor Circle
Brea, California 92821

Re: K240688
Trade/Device Name: RODIN Titan 3D Resin
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI, EBF
Dated: March 12, 2024
Received: March 13, 2024

Dear Daniel Gallegos:

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.

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
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240688

Device Name
RODIN Titan 3D Resin

Indications for Use *(Describe)*
Rodin Titan 3D Resin 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. It is indicated as a permanent restorative for both anterior and posterior restorations, including occlusal surfaces. It is used for fabricating permanent restorations such as inlays, onlays, veneers and full crown restorations.

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.

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510(k) Submission
RODIN Titan 3D Resin
510(k) Summary
K240688

Submitter:
Belport Company, Inc., Gingi-Pak
670 Endeavor Circle
Brea, CA 92821

Phone: (714) 990-5488

Contact Person: Daniel Gallegos

Date Prepared: April 25, 2024

Name of Device:	RODIN Titan 3D Resin
Common or Usual Name:	Tooth shade resin material
Regulation Number and Name:	21 CFR 872.3760, 21 CFR 872.3690
Product Code	EBI, EBF
Device Class	Class II
Primary Predicate	K230445, SprintRay OnX Tough
Secondary Predicate	K210412, Pac-Dent Ceramic Nanohybrid Resin

Device Description:
RODIN Titan 3D 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 RODIN Titan 3D 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 Rodin Titan 3D Resin is intended exclusively for professional dental work. RODIN Titan 3D 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
RODIN Titan 3D Resin 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. It is indicated as a permanent restorative for both anterior and posterior restorations, including occlusal surfaces. It is used for fabricating permanent restorations such as inlays, onlays, veneers and full crown restorations.

The intended use of fabrication of monolithic full and partial removable dentures is the same as the primary predicate device (K230445) (product code EBI) and the indication as a permanent restorative is the same as the secondary predicate device (K210412) (product code EBF). The intended use, technological characteristics, and critical specifications, of RODIN Titan 3D Resin are similar to the predicate devices.

Summary of Technological Characteristics
RODIN Titan 3D Resin and the primary (K230445) and secondary (K210412) predicate devices are all 3D printed denture devices. The liquid resin is polymerized in the 3D printer, which creates the final denture device. Here is a more detailed explanation of the process:

<u>RODIN Titan 3D Resin, Primary Predicate Device, and Secondary 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.

RODIN Titan 3D Resin, the primary predicate device, and the secondary 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 principles of operation are essentially similar; therefore, the RODIN Titan 3D Resin is substantially equivalent to its predicate devices.

Performance Requirements:

RODIN Titan 3D Resin conforms to the requirements of ISO 4049:2009 (Dentistry — Polymer-based restorative materials), ISO 20795-1: 2013 (Dentistry – Base Polymers) and EN ISO10993-1/ISO 7405 (Biological evaluation of medical devices).

Table 1. Physical Properties of Subject Device*:

Property	Specification	Result	Testing Protocols
Tooth Shades	N/A	BL, B1, A1, A2	N/A
Compressive Strength (MPa)	N/A	368 MPa	ASTM D695-15
Flexural Strength (MPa)	≥65 MPa	136 MPa	ISO 20795-1: 2013
Elastic Modulus (GPa)	≥2.0GPa	6.235 GPa	ISO 20795-1: 2013
Wavelength (nm) for Curing	N/A	380 nm	N/A
**Depth of Cure (mm)	N/A	N/A	N/A
Filler particle size distribution (μ)	N/A	3 μ	N/A
**Curing Time (sec)	N/A	N/A	N/A
***Release Profile (μ g/mm^3)	N/A	N/A	N/A
****Working Time (sec)	N/A	N/A	N/A
****Setting Time (min)	N/A	N/A	N/A
Stress Intensity Factor	Kmax ≥ 1.9 MPa m½	4.15 MPa m½	ISO 20795-1: 2013
Density	N/A	1.59 g/cm^3	N/A
Viscosity	N/A	1500 cP	N/A
Total Fracture Work	≥900 J/m^2	2442 (J/m^2)	ISO 20795-1: 2013
Hardness	N/A	95 Shore D	ASTM D2240
Water Solubility	≤1.6 µg/mm^3	0.1 µg/mm^3	ISO 20795-1: 2013
Water Sorption	≤32 µg/mm^3	26 µg/mm^3	ISO 20795-1: 2013
Opacity	N/A	70% @ 1mm thickness	N/A
Radiopacity	> 100 mm Al	200 mm Al	ISO 4049: 2009
Layer Thickness	N/A	100µm	N/A
Biocompatibility	Cytotoxicity	Comply	ISO 7405

Property	Specification	Result	Testing Protocols
Biocompatibility	Sensitization	Comply	ISO 7405
Biocompatibility	Irritation	Comply	ISO 7405
Biocompatibility	Acute Systemic Toxicity	Comply	ISO 7405
Biocompatibility	Genotoxicity	Unknown	ISO 7405
Biocompatibility	Subacute/Subchronic Systemic Toxicity	Unknown	ISO 7405
	*Post-cured in Otoflash for 5000 flashes		
	**Depth of Cure and Curing Time are dependent on the additive CAD/CAM printer, set by the manufacturer.		
	***The resin does not contain any releasable agent.		
	****Working time and setting time are not applicable because the resin is instantly cured and solidified by a light source, the photo initiation reaction occurs instantly without additional working time.		

Equivalence to Marketed Devices

The following table compares technological and other characteristics of the subject, primary predicate, and secondary predicate device.

Table 2. Comparison of Technological Characteristics with Predicates

Parameter	**Subject Device** RODIN Titan 3D Resin (K240688)	**Primary Predicate Device** SprintRay OnX Tough (K230445)	**Secondary Predicate Device** Pac-Dent Ceramic Nanohybrid Resin (K210412)	**Substantial Equivalence with Predicate Devices**
Manufacturer	Belport Company, Inc., Gingi-Pak	SprintRay Inc.	Pac-Dent, Inc.	
Product Code	EBI, EBF	EBI, PZY	EBF	Substantially equiv.
Regulation Number	872.3760, 872.3690	872.3760, 872.3590	872.3690	Substantially equiv.

Parameter	**Subject Device** RODIN Titan 3D Resin (K240688)	**Primary Predicate Device** SprintRay OnX Tough (K230445)	**Secondary Predicate Device** Pac-Dent Ceramic Nanohybrid Resin (K210412)	**Substantial Equivalence with Predicate Devices**
Regulatory Class	Class II	Class II	Class II	Substantially equiv.
Indication for use	RODIN Titan 3D Resin 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. It is indicated as a permanent restorative for both anterior and posterior restorations, including occlusal surfaces. It is used for fabricating permanent restorations such as inlays, onlays, veneers and full crown restorations.	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.	Pac-Dent Ceramic Nanohybrid Resin is indicated as a permanent restorative for both anterior and posterior restorations, including occlusal surfaces. It is used for fabricating permanent restorations such as inlays, onlays, veneers and full crown restorations.	Substantially equiv.

Parameter	**Subject Device** RODIN Titan 3D Resin (K240688)	**Primary Predicate Device** SprintRay OnX Tough (K230445)	**Secondary Predicate Device** Pac-Dent Ceramic Nanohybrid Resin (K210412)	**Substantial Equivalence with Predicate Devices**
User Population	Clinicians in dental offices	Clinicians in dental offices	Clinicians in dental offices	Substantially equiv.
Technology	3D liquid (light-cured) print resin for dental CAD/CAM	3D liquid (light-cured) print resin for dental CAD/CAM	3D liquid (light-cured) print resin for dental CAD/CAM	Substantially equiv.
Material	Methacrylate polymer resin (dimethacrylate)	Methacrylate Monomer/oligomers that polymerized to Methymethacylate Based polymer	Methacrylate polymer resin (dimethacrylate)	Substantially equiv.
Material Shades	BL, B1, A1, A2	Unknown	Bleach, A1, A2, A3, B1	Substantially equiv.
Biocompatible	Yes	Yes	Yes	Substantially equiv.
OTC or Rx	Rx	Rx	Rx	Substantially equiv.
Sterile	Non-sterile	Non-sterile	Non-sterile	Substantially equiv.
	Chemical Composition			
Chemical composition	UDMA HEMA BHT TPO TF 3.0 YbF3 Fumed Silica	Methacrylate polymer resin with photo initiator, inhibitor and pigments	UDMA HEMA BHT TPO TF 3.0 YbF3 Fumed Silica	Substantially equiv.
	Non-Clinical Performance Test Data			
Performance Testing	ISO 20795-1 ISO 4049:2009	ISO 20795-1	ISO 4049:2009	Substantially equiv.
Compressive Strength (MPa)	368 MPa	Unknown	378 MPa	Substantially equiv.
Flexural Strength (MPa)	136 MPa	126 MPa	112 MPa	Substantially equiv.
Elastic Modulus (GPa)	6.235 GPa	4.281 GPa	10.380 GPa	Substantially equiv.

Parameter	**Subject Device** RODIN Titan 3D Resin (K240688)	**Primary Predicate Device** SprintRay OnX Tough (K230445)	**Secondary Predicate Device** Pac-Dent Ceramic Nanohybrid Resin (K210412)	**Substantial Equivalence with Predicate Devices**
Wavelength (nm) for Curing	380 nm	380 nm	380 nm	Substantially equiv.
Depth of Cure (mm)	N/A	N/A	N/A	
Filler particle size distribution (μ)	3 μ	N/A	2 μ	Substantially equiv.
Curing Time (sec)	N/A	N/A	N/A	
Light intensity for curing (mW/cm^2)*	8.0 +/-0.5 mW/cm2	Unknown	8.0 +/-0.5 mW/cm2	Substantially equiv.
Stress Intensity Factor / Fracture Toughness (MPa • m½)	4.15 MPa • m½	3.38 MPa • m½	3.4 MPa • m½	Substantially equiv.
Water Sorption ($\mu g/mm^3$)	26 $\mu g/mm^3$	30 $\mu g/mm^3$	15.8 $\mu g/mm^3$	Substantially equiv.
Water Solubility ($\mu g/mm^3$)	0.1 $\mu g/mm^3$	3.5 $\mu g/mm^3$	0.4 $\mu g/mm^3$	Substantially equiv.
Density	1.59 g/cm^3	Unknown	1.78 g/cm3	Substantially equiv.
Viscosity	1500 cP	Unknown	2000 cP	Substantially equiv.
Total Fracture Work	2442 J/m^2	1033 J/m^2	964 J/m^2	Substantially equiv.
Hardness	95 Shore D	Unknown	99 Shore D	Substantially equiv.
Opacity	70% @ 1mm thickness	Unknown	68% @ 1mm thickness	Substantially equiv.
Radiopacity (mm of Al)	200 mm	Unknown	200 mm	Substantially equiv.

Parameter	**Subject Device** RODIN Titan 3D Resin (K240688)	**Primary Predicate Device** SprintRay OnX Tough (K230445)	**Secondary Predicate Device** Pac-Dent Ceramic Nanohybrid Resin (K210412)	**Substantial Equivalence with Predicate Devices**
Layer Thickness	100 µm	100 µm	100 µm	Substantially equiv.
Monomer Methyl Methacrylate (≤2.2%)	Pass	Pass	Pass	Substantially equiv.

* Intensity, Wavelength and Depth of Cure for Curing are dependent on the additive CAD/CAM printer, set by the manufacturer. The photo initiator, TPO exhibits an absorption spectrum at 380nm.

**The resin does not contain any releasable agent.

***Working time and setting time are not applicable because the resin is instantly cured and solidified by a light source, the photo initiation reaction occurs instantly without additional working time.

Table 3. Comparison of Biocompatibility with Predicates

Biocompatibility Parameter	**Subject Device**	**Primary Predicate Device**	**Secondary Predicate Device**	**Substantial Equivalence with Predicate Device**
Cytotoxicity (ISO 7405)	Pass	Pass	Pass	Substantially equiv.
Sensitization (ISO 7405)	Pass	Pass	Pass	Substantially equiv.
Irritation (ISO 7405)	Pass	Pass	Pass	Substantially equiv.
Acute Systemic Toxicity (ISO 7405)	Pass	Pass	Pass	Substantially equiv.
Genotoxicity (ISO 7405)	Unknown	Pass	Unknown	
Subacute/Subchronic Systemic (ISO 7405)	Unknown	Unknown	Unknown	

Table 4. Subject Device Performance Comparison at different build orientation

RODIN Titan (K240688)	**Specification**	0°	45°	60°	90°
Visual Appearance	Homogenous	Pass	Pass	Pass	Pass
Flexural Strength (MPa)	> 50	136	131	128	141
Elastic Modulus (GPa)	N/A	6.235	5.937	5.792	6.004
Stress Intensity Factor ($MPa*m^{1/2}$)	≥1.9	4.2	4.0	3.9	4.2
Total fracture work (J/m^2)	≥900	2242	2198	2031	2376

Table 5. Predicate Device Performance Comparison at different build orientation

OnX Tough (K230445)	**Specification**	0°	45°	60°	90°
Visual Appearance	Homogenous	Pass	Pass	Pass	Pass
Flexural Strength (MPa)	> 50	71	75	69	74
Elastic Modulus (GPa)	N/A	4.271	4.407	4.097	4.512
Stress Intensity Factor ($MPa*m^{1/2}$)	≥1.9	3.2	3.4	3.0	3.3
Total fracture work (J/m^2)	≥900	945	1002	892	990

Table 6. Subject Device Performance Comparison between different printers

RODIN Titan (K240688)	**Specification**	Asiga Max	Pro 4K
Visual Appearance	Homogenous	Pass	Pass
Flexural Strength (MPa)	> 50	135	138
Elastic Modulus (GPa)	N/A	5.937	6.126
Stress Intensity Factor ($MPa*m^{1/2}$)	≥1.9	4.1	4.2
Total fracture work (J/m^2)	≥900	2337	2496

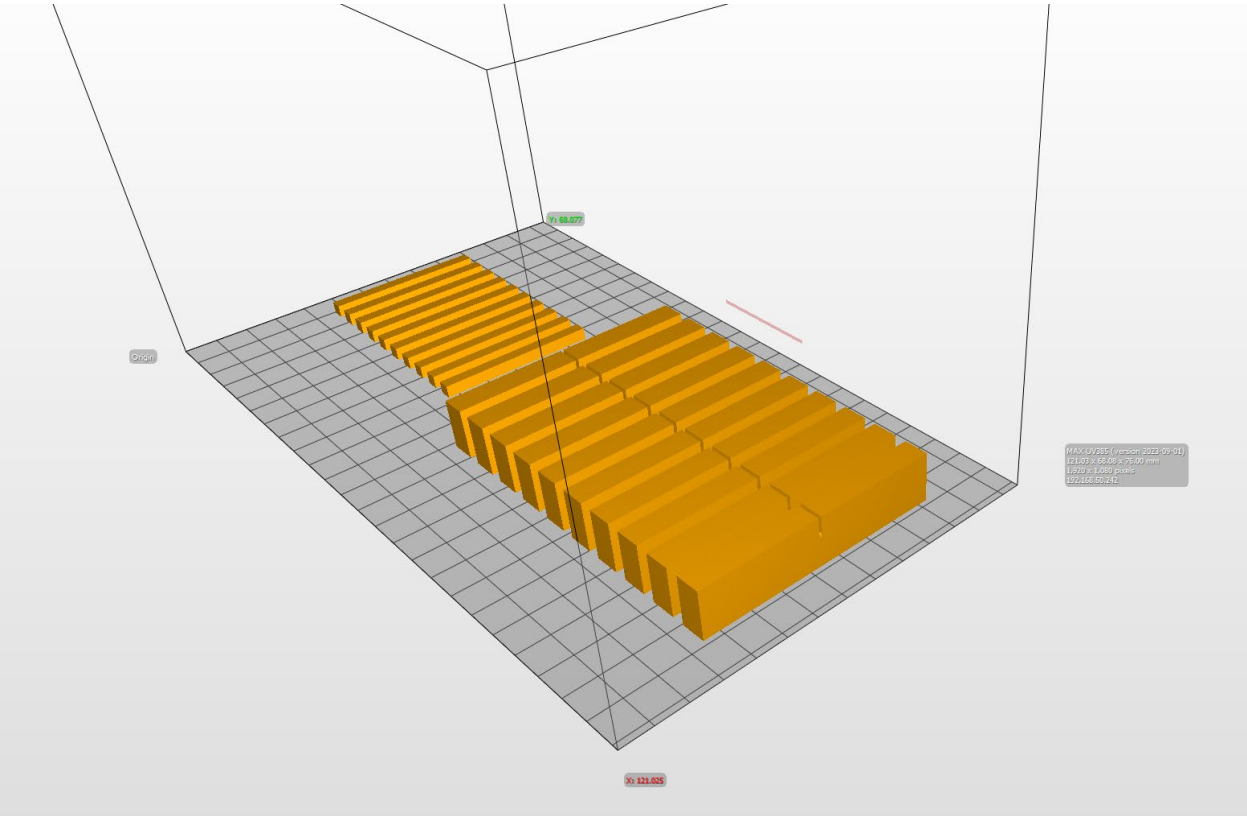

Figure 1. RODIN Titan worst-case build orientation testing at ninety degrees.

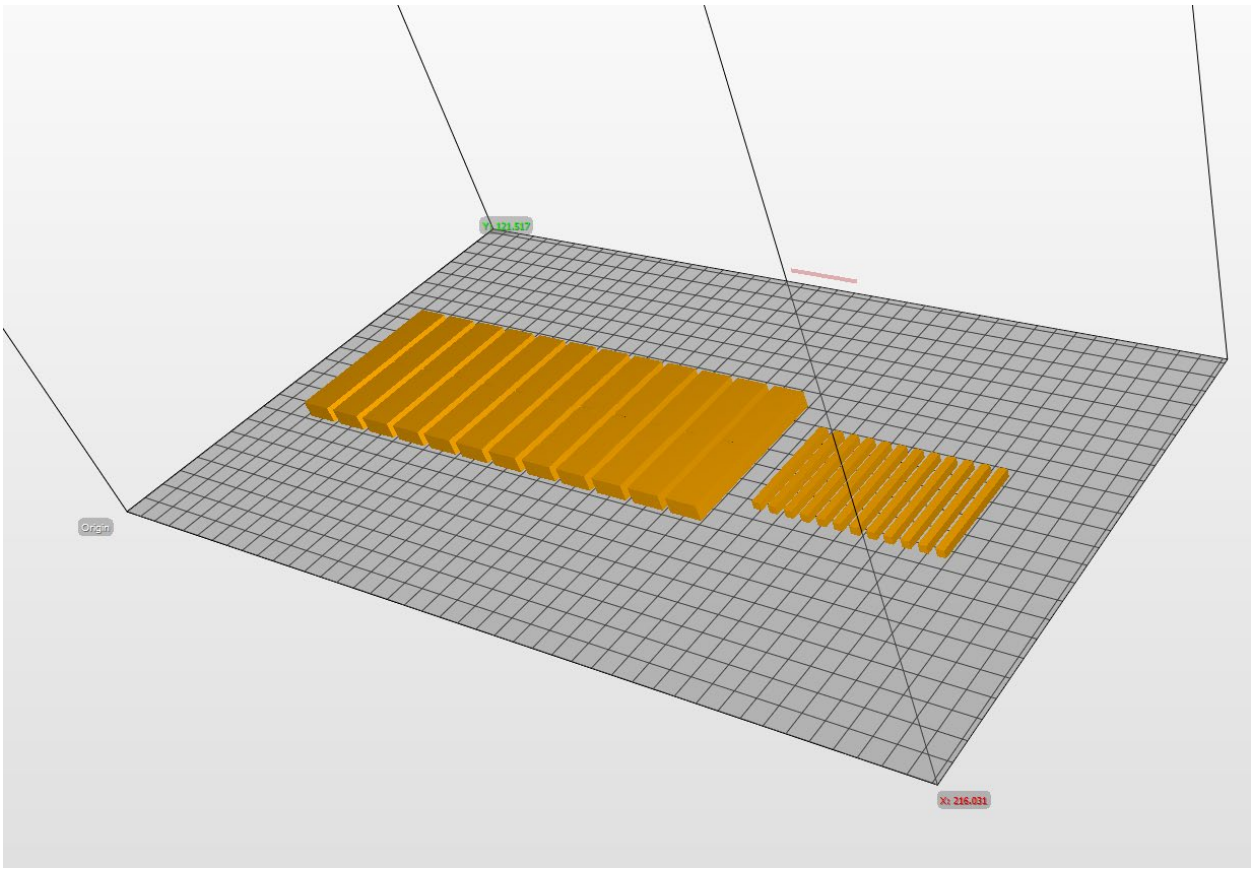

Figure 2. RODIN Titan worst-case build orientation testing at zero degrees.

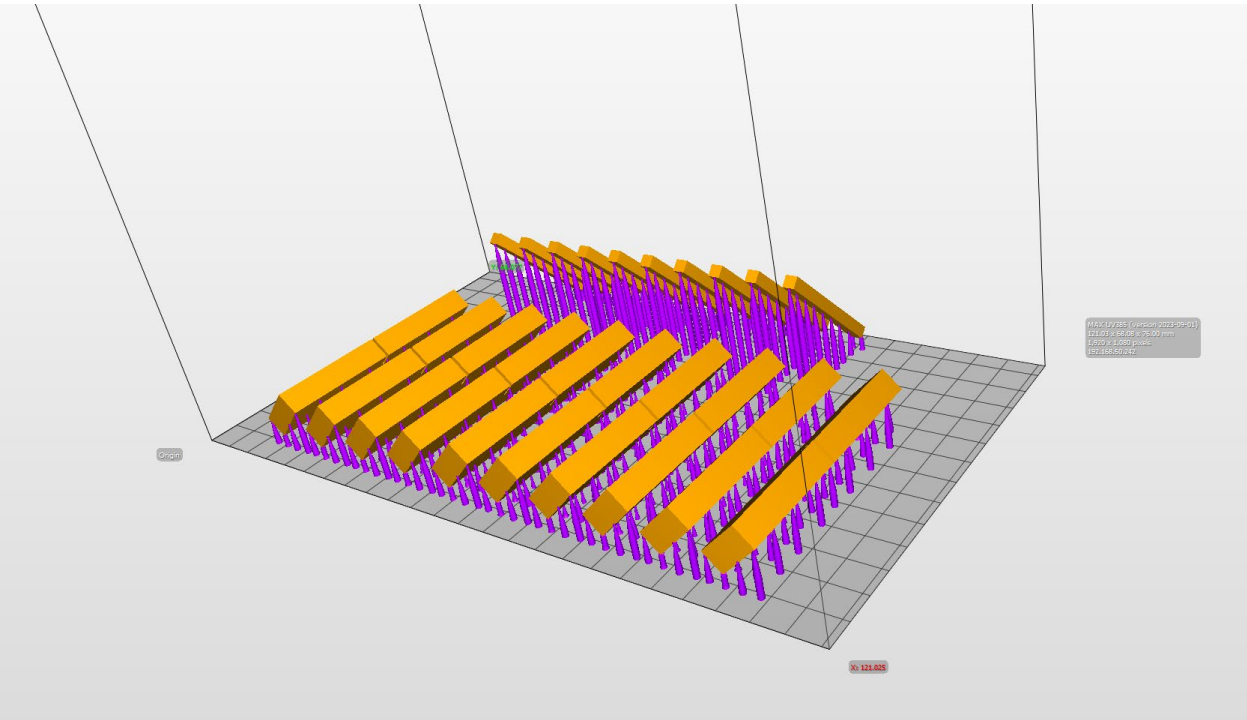

Figure 3. RODIN Titan worst-case build orientation testing at forty-five degrees.

Conclusions

The RODIN Titan 3D Resin is as safe and effective as its predicate devices. The RODIN Titan 3D Resin has the same intended use and indication, and similar technological characteristics as its predicate devices. The minor technological differences between the RODIN Titan 3D Resin and its predicate devices raise no new issues of safety and effectiveness. Performance data demonstrate that the RODIN Titan 3D Resin is as safe and effective as the predicate devices. Thus, the RODIN Titan 3D Resin is substantially equivalent.