July 7, 2022

Stratasys Ltd
% Melissa Burbage
Senior Regulatory Specialist
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K220771
Trade/Device Name: Stratasys TrueDent
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI, EBG, PZY, EBF
Dated: April 7, 2022
Received: April 8, 2022

Dear Melissa Burbage:

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,

For Michael E. Adjodha, M.ChE.
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)*
K220771

Device Name

Stratasys TrueDent™

Indications for Use *(Describe)*

Stratasys TrueDent™ is a light-curable resin indicated for the fabrication of dental appliances including removable full and partial dentures, denture bases, denture teeth, bridges, crowns, inlays, onlays, and veneers in dental laboratories. The material is an alternative to traditional heat-curable and auto polymerizing resins. Stratasys TrueDent™ 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.

510(k) Summary

K220771

Stratasys TrueDent™

Stratasys Ltd.

July 6, 2022

ADMINISTRATIVE INFORMATION

Manufacturer Name	Stratasys Ltd. 1 Holtzman Street St. Science Park P.O. Box 2496 Rehovot, 7612401, Israel Telephone: +972-74-745-4000 Fax: +972-74-745-4001
Official Contact	Melanie Glennon, VP Quality & Regulatory Affairs
Representative/Consultant	Melissa Burbage, Senior Regulatory Specialist Kevin A. Thomas, PhD; Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 858-792-1235 Fax: +1 858-792-1236 Email: mburbage@paxmed.com kthomas@paxmed.com, flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Device Name	Stratasys TrueDent™
Common Name	Resin, Denture, Relining, Repairing, rebasing
Regulation Number	21 CFR 872.3760
Regulation Name	Denture Relining, Repairing, or Rebasing Resin
Regulatory Class	Class II
Product Code	EBI
Secondary Product Codes	EBG, PZY, EBF
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (OHT 1: Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Health Technology 1 B (Dental and ENT Devices)

PREDICATE DEVICE INFORMATION

Primary Predicate:
K210977, E-Dent 1000 (Flexcera Base & Smile), EnvisionTEC GmbH

Reference Devices:
K203641, E-Denture Pro Resin, EnvisionTEC E-Denture Pro
K201827, GR-17 Resin System, Pro3dure Medical GmbH

INDICATIONS FOR USE STATEMENT

Stratasys TrueDent™ is a light-curable resin indicated for the fabrication of dental appliances including removable full and partial dentures, denture bases, denture teeth, bridges, crowns, inlays, onlays, and veneers in dental laboratories. The material is an alternative to traditional heat-curable and auto polymerizing resins. Stratasys TrueDent™ is intended exclusively for professional dental work.

SUBJECT DEVICE DESCRIPTION

Stratasys TrueDent™ is a light-curable methacrylate-based resin, that enables fabrication of monolithic, high quality, functional, and aesthetic dental appliances, including full and partial removable dentures, denture bases, denture teeth, bridges, crowns, inlays, onlays and veneers in a CAD/CAM additive manufacturing process. This material is intended to be used by trained dental professionals for the fabrication of various dental appliances in a CAD/CAM additive manufacturing process that includes the following components: digital dental files based on a digital impression, a Stratasys Poly Jet 3D printer, and curing light equipment. It is an alternative to traditional heat cured and auto polymerization resins. The predesigned color of the dental appliance is achieved by digitally mixing colored resins. The resins are available in five (5) different base colors (clear, white, cyan, magenta, and yellow). Stratasys TrueDent can be used only with Stratasys J5 Series printers. Stratasys J5 Series printers include a 3D printing system that utilizes PolyJet technology, with drop-on-demand inkjet printing process, 3 print heads, and a UV LED (395nm) curing process. The dental appliance is then cured in the Stratasys TrueDent™ Cure curing chamber and sent back to the dentist for try-in and final adjustment.

PERFORMANCE DATA

Non-clinical testing data submitted to demonstrate substantial equivalence included: shelf life testing, biocompatibility testing, performance testing according to ISO 10477, ISO 4049, and ISO 20795, and other performance tests based on internal procedures. Biological test considerations for this categorization include cytotoxicity, sensitization, irritation, acute systemic toxicity, sub-chronic toxicity, implantation, and genotoxicity.

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 performed. Additional equipment post-510(k) clearance will be added to the labeling by means of the Quality System and within the company's validation plan.

Stratasys TrueDent has a shelf life of 12 months with on-going real-time validation testing for an ultimate shelf life of 24 months. The shelf-life testing is conducted with bench tests from ISO 20795 and other performance tests based on internal procedures.

EQUIVALENCE TO MARKETED DEVICES

Indications for Use Statements

The subject device is indicated for fabrication of dental appliances, including removable full and partial dentures, denture bases, denture teeth and temporary bridges, in dental laboratories. The primary predicate (K210977) also has indications for individual and fixed permanent full single crowns, permanent partial crowns (also known as inlays and onlays) in anterior and posterior region, individual and fixed single veneers, artificial teeth for dental prostheses, individual and removable monolithic full and partial dentures. The slight differences in the language of the subject and primary predicate Indications for Use statements, however, do not affect the intended use. The main difference is that the subject device includes indications for bridges, which is not included in the indications of the primary predicate but is addressed by the reference device K201827. The Indications for Use for both the subject device and primary predicate include statements that the material is an alternative to traditional light-curable resin and is intended exclusively for professional dental work. Both the subject device and primary predicate require fabrication of these devices using a computer aided design and manufacturing (CAD/CAM) system. The subject device Indications for Use Statement does not list the process components, as it is not necessary that such components be listed in the Statement,

The indications for the reference device K203641 include fabrication of denture bases in dental laboratories for full removable dentures. This is the same indication as the subject device for full removable dentures. Slight differences in the language of the Indications for Use statements for the subject device and the reference device K203641 do not affect the intended use. Both the subject device and the reference device K203641 include statements that the material is an alternative to traditional light-curable and is intended exclusively for professional dental work. Both the subject device and the reference device K203641 require fabrication of these devices using a computer aided design and manufacturing (CAD/CAM) system.

The indications for the reference device K201827 include fabrication of temporary anterior dental restorations, temporary dental restorations and preformed denture teeth to be used in a denture. This is the same as the subject device for bridges and denture teeth, however, different language is used. Both the subject device and reference device K201827 include statements that the material is an alternative to traditional light-curable resin and is intended exclusively for professional dental work. Both the subject device and reference device K201827 require fabrication of these devices using a computer aided design and manufacturing (CAD/CAM) system, also known as additive manufacturing. The system component that is specified for reference device K201827 is an extra-oral curing light equipment.

Mechanical and Biological Properties

The physical, mechanical, and chemical properties of the subject device, the primary predicate device (K210977) and the two reference devices (K203641 and K201827) are very similar. They all are light-curable, methacrylate-based resins that are cured by UV light. They are all delivered in the form of a liquid intended to be used in additive manufacturing.

The subject device, the primary predicate device (K210977), and the two reference devices (K203641 and K201827) are all used in additive manufacturing processes. The type of printing process for reference device K201827 is unknown as it is not stated in the 510(k) Summary. The subject device, the primary predicate device (K210977), and reference device K203641 utilize a photopolymer resin 3D printing process that prints the material layer by layer. These are similar in that the print geometry is exposed to UV light that cures the material. The subject device is different in that it uses drop on demand (DOD) printing and the primary predicate device (K210977) and reference device K203641 use digital light processing (DLP) printing. DOD and DLP printing are similar in that they both use voxels for printing

resolution, print using similar materials (resin), cure the resin with UV light, and print support structures that are removed after printing. The main difference is how the material is printed.

DLP uses a vat of resin and a digital light projector to build parts. The projector flashes UV light onto the layer of resin, selectively solidifying the part. This exposure cures and solidifies the pattern and joins the material to the layer below as the build platform is lowered to create the next layer. To ensure good print quality in monolithic full dentures, support structures are built using the same material as the printed part and are removed during post processing. DLP uses the same material color for the entire fabrication, which requires post-processing to apply esthetic treatment (coloring).

DOD printing, as used for the subject device resin, works like an inkjet printer. The printer builds parts by jetting photopolymer droplets onto a build platform and solidifying them with UV light. The printer builds layer on top of layer. Similarly to DLP, support structures are also built to ensure good print quality, however a different material is used for the support material, which is also removed after the printing process. DOD printing allows different colors (same base resin with color agent) to be printed at the same time, which allow esthetic denture bases and teeth to be printed together, eliminating the secondary step of applying light curing color composite pastes or liquids to provide an esthetic result.

The differences in printing technology do not raise different questions of safety and effectiveness, as all manufacturing technologies produce a dental device from light-curing acrylic resins that may appropriately be characterized using standard FDA-recognized mechanical testing and biocompatibility evaluation. Performance testing and biocompatibility testing and evaluation were conducted 220771as appropriate mitigation measures for evaluation of substantial equivalence of the subject device, predicate device and reference devices, and the results demonstrate that the subject device is substantially equivalent.

For mechanical properties, the subject device as well as the primary predicate and both reference devices were tested in accordance with ISO 20795, ISO 4049, and ISO 10477. The subject device meets the requirements of these standards for flexural strength, flexural modulus, sorption, and solubility, similar to the primary predicate and both reference devices. The flexural strength meets the requirements of ISO 20795, ISO 4049, and ISO 10477, and results are similar to those of the primary predicate. The flexural modulus meets the requirements of ISO 20795 and ISO 4049, and results are similar to those of reference device K201827. The sorption and solubility meet the requirements of ISO 20795, ISO 4049, and ISO 10477, and results are similar to those of reference device K201827 (these values are not available for the primary predicate device and reference device K203641). The mechanical properties results demonstrate that the subject device is substantially equivalent to the predicate and reference devices.

Biocompatibility studies were performed on the subject device in accordance with ISO 7405 and ISO 10993. The subject device is categorized, according to ISO 7405 as a surface device with permanent contact. Biological test considerations for this categorization include cytotoxicity, sensitization, irritation, acute systemic toxicity, sub-chronic toxicity, implantation, and genotoxicity. The subject device was successfully evaluated for all such considerations using testing and scientific rationale. Based on the completed test results, the subject device is deemed biocompatible and meets the requirements of ISO 10993-1. Results of biocompatibility evaluation and testing demonstrate that the subject device is substantially equivalent to the predicate and reference devices.

Feature	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Conclusion
	Stratasys TrueDent™ Stratasys, Ltd.	E-Dent 1000 EnvisionTEC GmbH K210977	E-Denture Pro Resin EnvisionTEC GmbH K203641	GR-17 Resin System Pro3dure Medical GmbH K201827	
Product Code	EBI, EBG, PZY, EBF	EBF, EBI, ELM	EBI	EBG, PZY	Similar
Regulation	872.3760: Resin, Denture, Relining, Repairing, Rebasing 872.3770: Crown And Bridge, Temporary Resin 872.3590: Denture, Plastic, Teeth 872.3690: Material, Tooth Shade, Resin	872.3690: Material, Tooth Shade, Resin 872.3760: Resin, Denture, Relining, Repairing, Rebasing 872.3590: Denture, Plastic, Teeth	872.3760: Resin, Denture, Relining, Repairing, Rebasing	872.3770: Crown and Bridge, Temporary Resin 872.3590: Additively Manufacture, Preformed, Resin Denture Teeth	Similar
Intended Use	Removable full and partial dentures, denture bases, denture teeth, bridges, crowns, inlays, onlays, and veneers dental laboratories.	• Individual and fixed permanent full single crowns, permanent partial crowns in front and posterior area, • Individual and fixed single veneers, • Artificial teeth for dental prostheses, which are used for removable permanent full dentures, • Individual and removable monolithic full and partial dentures	Removable full dentures	Temporary anterior dental restorations (crown and bridge) and denture teeth.	Similar

Indications	Stratasys TrueDent™ is a light-curable resin indicated for the fabrication of dental appliances including removable full and partial dentures, denture bases, denture teeth, bridges, crowns, inlays, onlays, and veneers in dental laboratories. The material is an alternative to traditional heat-curable and auto polymerizing resins. Stratasys TrueDent™ is intended exclusively for professional dental work.	E-Dent 1000 is a light-curable resin indicated for the fabrication of: • individual and fixed permanent full single crowns, permanent partial crowns in front and posterior area, • individual and fixed single veneers, • artificial teeth for dental prostheses, which are used for removable permanent full dentures, • individual and removable monolithic full and partial dentures in dental laboratories. The material is an alternative to traditional restorative dental material. E-Dent 1000 is intended exclusively for professional dental work. Fabrication of dental applications with E-Dent 1000 requires a computer aided and manufacturing (CAD/CAM) system that includes the following components: digital dental files based on a digital impression or in case of artificial teeth for dental prostheses the digital dental files based on manufacturer's data, a digital light processing (DLP) printer, and curing light equipment.	E-Denture Pro is a light-curable resin indicated for the fabrication of denture bases fabricated in dental laboratories for full removable dentures. The material is an alternative to traditional heat-curable and auto polymerizing resins. E-Denture Pro is intended exclusively for professional dental work. Fabrication of denture bases with E-Denture Pro requires a computer-aided and manufacturing (CAD/CAM) system that includes the following components: digital denture base files based on a digital impression, a digital light processing (DLP) printer, and curing light equipment.	The GR-17 Resin System is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment. The GR-17 temporary is indicated for the fabrication, by additive manufacturing, of temporary anterior dental restorations. The GR-17.1 temporary is indicated for the fabrication, by additive manufacturing, of temporary dental restorations, and for the fabrication, by additive manufacturing, of preformed denture teeth to be used in a denture.	Similar
Chemical Description	Methacrylate-based resin	Methacrylate-based resin	Methacrylate-based resin	Methacrylate-based resin	Same
Material Type	Light-curable Resin	Light-curable Resin	Light-curable Resin	Light-curable Resin	Same
Curing Method	UV Light	UV Light	UV Light	UV Light	Same
Product State	Liquid	Liquid	Liquid	Liquid	Same
Manufacturing Technology Type	Additive	Additive	Additive	Additive	Same
Product Characteristics					
Standards	ISO 10477 ISO 4049 ISO 20795	ISO 10477 ISO 4049 ISO 20795	ISO 20795	ISO 10477 ISO 4049 ISO 22112	Similar
Physical and Mechanical Properties	Flexural Strength Flexural Modulus Sorption Solubility	Flexural Strength Flexural Modulus Sorption Solubility	Flexural Strength Flexural Modulus Sorption Solubility	Flexural Strength Flexural Modulus Sorption Solubility	Same
Biocompatibility Standards	ISO 7405 ISO 10993	ISO 10993	ISO 10993	ISO 7405 ISO 10993	Similar

	Cytotoxicity (Part 5) Sensitization (Part 10) Irritation (Part 10) Systemic Toxicity (Part 11) Genotoxicity (Part 3)	Cytotoxicity (Part 5) Sensitization (Part 10) Irritation (Part 10) Systemic Toxicity (Part 11)	Cytotoxicity (Part 5) Sensitization (Part 10) Irritation (Part 10) Systemic Toxicity (Part 11)		
Workflow					
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 performed.	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 performed.	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 performed.	Not stated in summary	Similar
Printer	Stratasys J5 DentaJet	EnvisionTECs Perfactory® 3D-Printer DLP models designed and validated for use with the E-Dent 1000 light cured resin are: • EnvisionOne cDLM,with LED • Micro series, with LED • Vida Series, with LED • P4K Series, with LED • D4K Series, with LED	EnvisionTECs Perfactory® 3D-Printer models designed and validated for use with the E-Denture Pro light cured resin are: EnvisionOne cDLM, with LED Vida Series, with LED P4K Series, with LED D4K Series, with LED	Not stated in summary	Similar
Post Cure	TrueDent™ Cure	Not listed in summary	Not listed in summary	Curing system such as Nyomo, Rapidshape, Envisiontec or Asiga Systems	Similar
How Provided					
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Same
Shelf Life	2 years (12 months at time of submission)	2 years (4 months at time of K210977)	3 years	2 years	Similar
Color options	5 colors	Base: 5 Shades Smile: 5 Shades	6 colors	7 shades	Similar

CONCLUSION

The subject device, the primary predicate device, and the reference devices have the same intended use, have similar technological characteristics, made of the similar materials, and manufactured using additive manufacturing processes. The data included in this submission demonstrate substantial equivalence to the primary predicate and reference devices.