April 13, 2023

Myerson, LLC
% Patsy Trisler
Regulatory Consultant
Trisler Consulting
306 Turnberry Court
Lebanon, Indiana 46052

Re: K230098
Trade/Device Name: Trusana™
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: January 11, 2023
Received: January 13, 2023

Dear Patsy Trisler:

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,

Michael E. Adjodha -S

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)*
K230098

Device Name

Trusana™

Indications for Use *(Describe)*

Trusana™ resin is intended to 3D print denture base for use in making removable full and partial dentures or overdentures. Trusana™ is intended exclusively for professional dental work. Fabrication of denture bases with Trusana™ requires a computer-aided and manufacturing (CAD/CAM) system using the Asiga MAX UV or Asiga PRO 4K 3D printer in conjunction with the Asiga Flash curing chamber.

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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K230098 - 510(k) Summary

I. SUBMITTER	
Submitter Name:	Myerson, LLC
Submitter Address:	5106 North Ravenswood Avenue Chicago, IL 60640-2713
Contact Person: Email:	James H. Swartout, President & CEO jswartout@myersontooth.com
Telephone:	312.432.8200
Date Prepared:	January 11, 2023

II. DEVICE	
Trade Name:	Trusana™
Common Name	Denture Resin
Classification: **Name | Number** **Product Code** **Device Class**	 Denture Relining, Repairing, or Rebasing Resin | 21 CFR 872.3760 EBI II

III. PREDICATE DEVICE	
Primary Predicate Device:	K191497, NextDent Denture 3D+, Vertex-Dental BV
Reference Device	none

IV. INDICATIONS FOR USE STATEMENT

Trusana™ resin is intended to 3D print denture base for use in making removable full and partial dentures or overdentures. Trusana™ is intended exclusively for professional dental work. Fabrication of denture bases with Trusana™ requires a computer-aided and manufacturing (CAD/CAM) system using the Asiga MAX UV or Asiga PRO 4K 3D printer in conjunction with the Asiga Flash curing chamber.

V. DEVICE DESCRIPTION

Device Identification	The Trusana device is a light-activated denture base resin, offered in four shades.
Technological Characteristics	The Trusana resin is used with patient-specific *.stl files provided by the dental practitioner to fabricate the customized denture bases for removable denture devices using a 3D (additive) printer and curing unit. The proprietary light-curable resin is composed of methylacrylated monomers, methacrylated carboxylic acid, phosphine oxide initiator and pigments for color It is used by dental laboratories and dental practices to make the denture bases for the removable dentures.

	The resin is offered in lightproof 1L high density polyethylene (HDPE) bottles. Trusana resin is an alternative material to heat-curable and auto-polymerizable resins.

VI. SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

	NEW DEVICE	PRIMARY PREDICATE
510(k) NUMBER; DEVICE NAME; MANUFACTURER	K230098 Trusana™ Myerson, LLC	K191497 NextDent Denture 3D+ Vertex-Dental BV
PRODUCT CODE REGULATORY NAME CLASSIFICATION	EBI Denture Relining, Repairing, or Rebasing Resin 21 CFR 872.3760	EBI Denture Relining, Repairing, or Rebasing Resin 21 CFR 872.3760
INDICATIONS FOR USE	Trusana™ resin is intended to 3D print denture base for use in making removable full and partial dentures or overdentures. Trusana™ is intended exclusively for professional dental work. Fabrication of denture bases with Trusana™ requires a computer-aided and manufacturing (CAD/CAM) system using the Asiga MAX UV or Asiga PRO 4K 3D printer in conjunction with the Asiga Flash curing chamber.	NextDent Denture 3D+ is a light-cured resin indicated for the fabrication of denture bases fabricated in dental laboratories, including full and partial removable dentures. The material is an alternative to traditional heat-cured and auto polymerization resins. NextDent Denture 3D+ is intended exclusively for professional dental work. Fabrication of denture bases with NextDent Denture 3D+ requires a computer-aided and manufacturing (CAD/CAM) system that includes the following scanner, design software, additive printer and post-cure unit: Design: Scanner: 3Shape D900 Design Software: 3Shape Dental-System 2016 Premium Printing: Printer: 3D Systems NextDent 5100 Figure 4®; Software: 3D Sprint Post-curing: Post-cure unit: NextDent LC-3D Print Box
INGREDIENTS	Light-curable Resin	Light-curable Resin
MANUFACTURING TECHNOLOGY TYPE	Additive	Additive
CURED PRODUCT CHARACTERISTICS:		
Sterility	Non-sterile	Non-sterile
Ultimate Flexural Strength	65 MPa or more (per ISO 20795-1)	84 MPa (per ISO 20795-1 – company website)

Flexural (Bending) Modulus	2000 MPa or more (per ISO 20795-1)	2383 MPa (per ISO 20795-1 – company website)
Water Sorption	32 µg/mm^3 or less (per ISO 20795-1)	28 µg/mm^3 (per ISO 20795-1 – company website)
Water Solubility	1.6 µg/mm^3 or less (per ISO 20795-1)	0.1 % (w/w) (per ISO 20795-1 – company website)
Residual monomer	0% (per ISO 20795-1)	<0.1% (w/w) (per ISO 20795-1 – company website)
Biocompatibility	Biocompatible, according to ISO 10993 testing	Biocompatible, according to ISO 10993 testing (per company website)

VII PERFORMANCE AND SAFETY TESTING	
Animal Testing:	This product category does not require animal testing.
Clinical Testing:	This product category does not require human clinical testing.
Laboratory Testing:	Testing was conducted to evaluate the performance of a manufactured denture base, according to requirements of DIN EN ISO 20795-1:2013, Dentistry – Base Polymers. The following specification requirements of the 3D-printed denture base material samples were tested and have been met: • Surface characteristics • Shape capability • Color and color stability • Translucency • Freedom from porosity • Ultimate Flexural strength • Flexural bending modulus • Bonding to synthetic teeth • Water Sorption • Solubility • Validation of no residual MMA monomer.
Shelf Life Testing:	Validated real-time shelf life of the Trusana resin at time of 510(k) submission is 13 months. Properties tested include chemical and physical characteristics after storage.
Biocompatibility Testing:	An assessment, according to ISO 10993-1, based on extractables and cytotoxicity testing, confirms that Trusana printed denture base is biocompatible and non-toxic and meets the requirements for a device in contact with mucosal membrane for >30 days.
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 Asiga machines.

	Further, tests based on considerations of the orientation during manufacturing were performed.

VIII COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES

The intended use, critical specifications, and additive method of manufacturing of Trusana are substantially equivalent to the predicate device, NextDent Denture 3D+.

While the resin of the predicate is different from Trusana, both are photo-curable resins used in additive manufacturing and are of the same material category.

The additive manufacturing processes both use a resin to fabricate the denture bases using a 3D printer, associated software and curing unit.

The noted differences, in comparison to the predicate device, raise no new questions of safety and effectiveness.

VIX CONCLUSION

Based on the comparisons provided and the data submitted in this 510(k), it can be concluded Trusana™ is substantially equivalent to the predicate device. Myerson's analysis of the resin and its output compared to the predicate show they have the same intended use and similar technological parameters that meet the requirements of ISO 20795-1:2013.