November 1, 2019

Vertex-Dental BV
℅ Patsy Trisler
Consultant
Qserve Group US Inc.
5600 Wisconsin Avenue
Chevy Chase, Maryland 20815

Re: K191497
Trade/Device Name: NextDent Denture 3D+
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: September 3, 2019
Received: October 2, 2019

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,

for Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191497

Device Name
NextDent Denture 3D+

Indications for Use *(Describe)*
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:

	Brand	Type	Software
Scanner	3Shape	D900	
Design software	3Shape	Dental-System 2016 Premium	

Printing:

	Brand	Type	Software
Printer	3D Systems	NextDent 5100 Figure4®	3D Sprint

Post-curing:

	Brand	Type	Software
Post-cure unit	NextDent	LC-3DPrint Box	n.a.

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.

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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."

K191497

Section 5.0

510(k) SUMMARY— NextDent Denture 3D+

I. SUBMITTER	
Submitter Name:	Vertex-Dental B.V.
Submitter Address:	Centurionbaan 190 3769 AV Soesterberg The Netherlands
Contact Person: Telephone #:	L. Vloet-Emonts +31 88 61 60 430
Date Prepared:	September 27, 2019
II. DEVICE	
Device Trade Name:	NextDent Denture 3D+
Common and Classification Name(s):	Resin, Denture
Classification #:	21 CFR 872.3760
Product Code	EBI
Regulatory Class	2
III. PREDICATE DEVICE(s)	NextDent Denture, K162572 No reference devices were used in this submission.
IV. DEVICE DESCRIPTION	
Device Identification:	Light-Cure Resin, provided in a container.
Device Characteristics:	NextDent Denture 3D+ dimethacrylic system, polymerized via photo initiators in a 3D printer setting. The color of the denture is determined by the addition of pigments.
Environment of Use:	• Healthcare facility/hospital • Dental (technical) laboratory.
Summary (Description) of Device:	NextDent™ Denture 3D+ must be used in combination with the NextDent™ 5100 Figure4® 3D printer. Printer and resin must be optimized to each other in order to get complete and precise printed parts. If printer and resin are not optimized to each other this may have an adverse effect on the accuracy and physical quality of printed parts. The NextDent™ 5100 Figure4® 3D printer and the post-curing lightbox NextDent™ LC-PrintBox make use of a light source to polymerize the NextDent resin. Therefore we advise to wear UV protective glasses when operating a 3D printer and/or lightbox. Differences in color nuance may occur due to: • production in batches; • inadequate shaking and mixing of

	• the original packaging before use; • inadequate stirring in the resin Denture 3D+ before use; • insufficient post-curing 3D printer is not included with the device.
Materials of Use:	methacrylate-based resins with photo-initiator, filler and pigments.

V. INDICATIONS FOR USE	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		
	Brand	Type
Scanner	3Shape	D900
Design software	3Shape	Dental-System 2016-Premium

Printing			
Printer	Brand	Type	Software
	3D Systems	NextDent 5100 Figure 4	3D Sprint

Post-Curing		
Post-cure unit	NextDent	LC-3DPrint Box

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both NextDent™ Denture 3D+ and the predicate device have the following similar characteristics:

- Pre-mixed light-cure resins with photo-initiator and pigments
- Polymerization by visible light
- Automated printing of resin in multiple layers, each light-cured before adding next layer, with post curing in light chamber
- Post curing by visible light-curing unit

The difference is in the chemical composition of the specific resin.

Technological characteristics	Predicate device: NextDent™ Denture			New device: NextDent™ Denture 3D+		
	Brand	Type	Software	Brand	Type	Software
Design:						
Scanner	3Shape	D900	Dental-System 2016-Premium	3Shape	D900	Dental-System 2016-Premium
Printing:						
Printer	Envision Tec	DDDP 4	Perfectory	3D Systems	NextDent 5100 Figure 4®	3D Sprint
	Rapid Shape	D30	Netfabb			
	Miicraft	125Y /	MiiUtility Miicontroller			
	3D Systems	Figure 4®	3D Sprint			
	Roland DG	DWP-80S	Ver1.1			
Post-Curing:						
Post-cure unit	NextDent™	LC-3DPrint box	n.a.	NextDent™	LC-3DPrint Box	n.a.

VII. SUMMARY OF TESTING [PERFORMANCE DATA]

NextDent™ Denture 3D+ has been tested for mechanical properties as part of the product specification. The most applicable standard for mechanical characteristics determination of denture base polymers and copolymers is the ISO 20975-1: 2013 Dentistry - Base polymers - Part 1: Denture base polymers.

Biocompatibility Testing:

According to ISO 7405:2008/A1:2013 NextDent™ Denture 3D+ is considered a surface device, in contact with the mucosal membrane, for > 30 days.

The ISO 10993-1:2009/C1:2010 standard, including parts 3, 5, 10 and 11, was followed and the following biological safety aspects have been addressed:

- Cytotoxicity
- Sensitization
- Irritation or intracutaneous reactivity
- Subacute/subchronic systemic toxicity
- Genotoxicity

	In addition, the following risks have been considered based on a risk assessment, taking into account the specific nature and duration of exposure to the device • Carcinogenicity • Reproductive/developmental/organ toxicity • Immunotoxicity Furthermore, it is demonstrated that • Re-use of print resin material (stored under the correct conditions) without the introduction of recycling steps can be used safely without impacting the biological safety • No monomers remain on the surface of the 3D printed parts before post-curing due to cleaning steps according to IFU NextDent Denture 3D+ is compliant to the requirements defined in ISO 10993-1/C1:2010, including parts 3, 5, 10 and 11, for permanent medical devices.
Bench Testing	NextDent Denture 3D+ has been tested for conformity with the industry standard ISO 20795-1:2013 Dentistry – Base polymers – Part 1: Denture base polymers. NextDent Denture 3D+ is compliant to the requirements defined in ISO 20975-1 for Type 4 materials. The following bench tests are conducted on NextDent Denture 3D+: • Ultimate Flexural strength • Flexural modulus • Water sorption • Water solubility • Residual monomer • Biocompatibility NextDent Denture 3D+ can be repeatedly and successfully printed on all NextDent 5100 Figure4® printers and complies to all requirements defined in ISO 20975-1 for Type 4 materials. The medical device may be printed with horizontal and vertical orientation independent of the build location in the build space, with the possibility to re-use resin, within 80% accuracy of 100 µm, with an worst-case average product density of 6.39 g/mm, at a temperature range of 18°C to 28°C.
Reprocessing, Sterility and Shelf-Life Testing	The device is provided non-sterile. From the Shelf life testing, NextDent Denture 3D+ has a shelf life of 2 years.
VIII. CONCLUSIONS	NextDent Denture 3D+ and the predicate have the same intended use and similar technological characteristics.

	The results of the performed tests show that NextDent Denture 3D+ meets the requirements mentioned in the applicable standards, and confirm that the device performs similarly to the predicate device. It is therefore concluded that NextDent Denture 3D+ is safe and performs as intended, and is substantially equivalent to the predicate device.