DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 30, 2017

Vertex-Dental BV
c/o Patsy J. Trisler, JD, RAC
Consultant
Qserve Group US Inc.
5600 Wisconsin Avenue
Chevy Chase, MD 20815

Re: K162572
Trade/Device Name: NextDent™ Denture/E-Denture
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: May 24, 2017
Received: May 24, 2017

Dear Patsy J. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Andrew I. Steen -S

for Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162572

Device Name

NextDent™ Denture / E-Denture

Indications for Use *(Describe)*

NextDent™ Denture / E-Denture 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 / E-Denture is intended exclusively for professional dental work. Fabrication of denture bases with NextDent ™ Denture / E-Denture requires a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer and post-cure unit.

NextDent™ Denture / E-Denture is compatible with the following CAD/CAM systems components:

Design:

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

Printing:

	Brand	Type	Software
Printer	EnvisionTEC	DDDP 4	Perfactory
	Rapidshape	D30	NetFabb
	Miicraft	125Y	MiiUtility MiiController
	3D systems	Figure 4	3D Sprint
	Roland DG	DWP-80S	Ver1.1

Post-Curing:

	Brand	Type
Post-Cure unit	NextDent ™	LC-3D PrintBox

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.

K162572

Section 5.0

510(k) SUMMARY— NextDent™ Denture / E-Denture

I. SUBMITTER	
Submitter Name:	Vertex-Dental B.V.
Submitter Address:	Centurionbaan 190 3769 AV Soesterberg The Netherlands
Contact Person: Telephone #:	O.F. Beckeringh van Loenen +31 88 6160416
Date Prepared:	June 29, 2017
II. DEVICE	
Device Trade Name:	• NextDent™ Denture • E-Denture
Common and Classification Name(s):	Resin, Denture, Relining, Repairing, Rebasing
Classification #:	21 CFR 872.3760
Product Code	EBI
Regulatory Class	2
III. PREDICATE DEVICE(s)	Dentca Denture Base, K143033 No reference devices were used in this submission.
IV. DEVICE DESCRIPTION	
Device Identification:	Light-Cure Resin, provided in a container.
Device Characteristics:	Denture Base Resins, Photo-Cured product family comprises a family of dimethacrylate resins. In general, the products in this family are composed of a 2-component 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 / E-Denture 3D-printing material is a light-cured resin indicated for the manufacturing of denture bases. The material is used in a 3D printer, which prints the shape determined by a 3D stereolithographic drawing. After printing, the printed product is placed in a UV-light curing box for final polymerization. 3D printer is not included with the device.
Materials of Use:	Dimethacrylate-based resins with photo-initiator, and pigments.

V. INDICATIONS FOR USE

NextDent™ Denture / E-Denture 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 / E-Denture is intended exclusively for professional dental work.

Fabrication of denture bases with NextDent™ Denture / E-Denture requires a computer-aided and manufacturing (CAD/CAM) system that includes the following; scanner, design software, additive printer, and post-cure unit.

NextDent™ Denture / E-Denture is compatible with the following CAD/CAM systems components:

Design:

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

Printing:

Printer	Brand	Type	Software
	EnvisionTEC	DDDP 4	Perfactory
	Rapidshape	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-*3D*Print Box

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Indications for Use statement of the predicated device Dentca Denture Base (K143033) is the following:

“Dentca Denture Base is a light-cured resin indicated for fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional heat cured and auto polymerizing resins.

Fabrication of dental prosthetics with Dentca Denture Base requires a computer-aided design and manufacturing (CAD/CAM) system that includes the following components not part of the device: oral casting impression, digital denture base file created in an optical impression system, stereolithographic additive printer, and curing light equipment.”

	Both NextDent™ Denture / E-Denture and the predicate device have the following similar characteristics: - Both devices are light-cure resins indicated for fabrication of removable full and partial denture bases. - Both devices require a CAD/CAM system consisting of a scanner, design software, additive printer and post-cure unit. NextDent™ Denture / E-Denture is not indicated for repair of dentures because in our opinion the stereolithographic technique is not indicated for repair of denture bases. The difference is in the chemical composition of the specific resin. NextDent™ Denture / E-Denture is similar to the predicate device in the method of processing. The main difference is the chemical composition of the resin. The chemical composition might influence the biocompatibility of NextDent™ Denture's / E-Denture's denture base, as well as its performance (mechanical properties). Thus, both biocompatibility and performance has been demonstrated for NextDent™ Denture / E-Denture. The same tests according to the same standards were used to show biocompatibility and performance of the predicate. It was concluded, therefore, that the technological differences do not raise different questions of safety and effectiveness. Based on the Device Comparison Table (section 12.2) and Comparison Demonstration Substantial Equivalence (section 12.3) it was concluded (section 12.4) that NextDent™ Denture / E-Denture, manufactured by Vertex-Dental, is substantially equivalent to the predicate device.
VII. SUMMARY OF TESTING [PERFORMANCE DATA]	NextDent™ Denture / E-Denture 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 Dentistry - Base polymers - Part 1: Denture base polymers.
Biocompatibility Testing:	NextDent™ Denture / E-Denture is considered a surface device, in contact with the mucosal membrane, for > 30 days.

The ISO 10993-1 standard was followed and the following biological safety aspects have been addressed:

- Cytotoxicity – ISO 10993-5
- Sensitization – ISO 10993-10
- Irritation or intracutaneous reactivity – ISO 10993-10
- Subacute/subchronic systemic toxicity – ISO 10993-3
- Genotoxicity – ISO 10993-3

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
- Presence of phthalates

Bench Testing

NextDent™ Denture / E-Denture has been tested for conformity with the industry standard ISO 20795-1.

NextDent™ Denture / E-Denture is compliant to the requirements defined in ISO 20975-1 for Type 4 materials, except for water solubility which value slightly exceeds the requirement for Type 4 materials, but meets the requirement for Type 2 materials.

NextDent™ Denture / E-Denture is compatible with the following CAD/CAM systems components:

Design:

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

Printing:

Printer	Brand	Type	Software
	EnvisionTEC	DDDP 4	Perfactory
	Rapidshape	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-*3D*Print Box

The following bench tests are conducted on NextDent™ Denture / E-Denture using all the

	compatible CAD/CAM systems, including the post curing process: • Flexural strength • Flexural modulus • Water sorption • Water solubility • Residual monomer • Biocompatibility
Sterility and Shelf-Life Testing	The device is provided non-sterile. From the Shelf life testing, NextDent™ Denture / E-Denture has a shelf life of 2 years. The shelf life testing has been conducted with the bench tests from the ISO standard 20975-1.
VIII. CONCLUSIONS	NextDent™ Denture / E-Denture and the predicate have the same intended use and similar technological characteristics. The results of the performed tests show that NextDent™ Denture / E-Denture 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 / E-Denture performs as intended, and is substantially equivalent to the predicate device.