October 20, 2023

Vertex-Dental B.V.
% Patsy Trisler, Jd, Rac
Consultant
Qserve Group US Inc.
350 S. Main Street
Doylestown, Pennsylvania 18901

Re: K231388
Trade/Device Name: NextDent Base
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: October 2, 2023
Received: October 2, 2023

Dear Patsy Trisler, Jd, Rac:

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,

FDA Bobak Shirmohammadi -S

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

K231388

Device Name
NextDent Base

Indications for Use *(Describe)*
NextDent Base is for dental professional use only and intended for the manufacturing of denture bases to support artificial teeth to form full or partial removable dentures.

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."

K231388
Section 5.0

510(k) SUMMARY— NextDent Base

I. SUBMITTER	
Submitter Name:	Vertex-Dental B.V.
Submitter Address:	Centurionbaan 190 3769 AV Soesterberg The Netherlands
Contact Person: Telephone #:	N.C. - Peterse – van der Koppel +31 88 61 60 430
Date Prepared:	October 20, 2023

II. DEVICE	
Device Trade Name:	NextDent Base
Common Name(s):	Resin, denture
Classification Name	Resin, denture, relining, repairing, rebasing
Product Codes	EBI
Regulatory Class	Class 2
Classification Regulation	21 CFR 872.3760

III. PREDICATE DEVICE(s)	NextDent Denture 3D+, K191497 (Primary Predicate)

IV. DEVICE DESCRIPTION	
Device Identification:	Light-Cure Resin, provided in a container.
Device Characteristics:	NextDent Base is a combination of acrylate-based light-cure resin with pigments, polymerized via photo initiators in a 3D printer setting for fabrication of denture bases to support artificial teeth to form full or partial removable dentures.
Environment of Use:	• Healthcare facility/hospital • Dental (technical) laboratory.
Summary (Description) of Device:	Fabrication of denture bases with NextDent Base requires a VAT based 3D printer that supports NextDent resins. Printer and resin must be optimized to each other to get complete and precise printed parts.

<table>
<tr><td></td><td>
<table>
<tr><th colspan="4">Printing</th></tr>
<tr><th>Printer</th><th>Brand</th><th>Type</th><th>Software</th></tr>
<tr><td></td><td>3D Systems</td><td>NextDent 5100 Figure 4</td><td>3D Sprint</td></tr>
<tr><th colspan="4">Post-Curing</th></tr>
<tr><th>Post-cure unit</th><th>Brand</th><th>Type</th><th>Software</th></tr>
<tr><td></td><td>NextDent</td><td>LC-3DPrint Box</td><td>n.a.</td></tr>
</table>
Fit of the parts strongly depends on design and library used. Features like undercuts and spacers should be taken in consideration when designing the parts.
Both the NextDent™ 5100 Figure4® 3D printer and the post-curing lightbox NextDent™ LC-3DPrint Box make use of a UV light source to polymerize the NextDent Base resin.
NextDent™5100 Figure4® 3D printer or NextDent™ LC-3DPrint Box is not included with the device.
Cured parts are finished using conventional dental methods and instruments. NextDent 3D printed cured parts should be cleaned with nonchemical products.
</td></tr>
<tr><td>Materials of Use:</td><td>A combination of acrylate-based resins with photo-initiator and pigments.</td></tr>
</table>

V. INTENDED USE / INDICATIONS FOR USE	NextDent Base is for dental professional use only and intended for the manufacturing of denture bases to support artificial teeth to form full or partial removable dentures.

VI. TECHNOLOGICAL CHARACTERISTICS	NextDent Base is a pre-mixed acrylate-based UV light-cure resin with pigments and polymerized via photo initiators in a 3D printer setting. Automated printing of the resin in multiple layers, each light-cured before adding next layer, are post-cured in the UV light chamber. The cured parts are finished using dental methods.

VII. COMPARISON TO THE PREDICATE DEVICE:	Both NextDent Base and the predicate device are resins intended for the manufacturing of 3D printed full and partial removable denture bases.
INTENDED USE:	Both devices are intended exclusively for professional dental work.
TECHNOLOGICAL CHARACTERISTICS:	Both NextDent Base and the predicate device have the following similar characteristics:

<table>
<tr><td></td><td>

Pre-mixed light-cure combination of acrylate-based resin with photo-initiator
Polymerization and post-curing by UV light
Automated printing of resin with the same 3D printer and software in multiple layers, each light-cured before adding next layer, with post curing in light chamber
Finished by using dental methods

<table>
<tr><td>Technological characteristics</td><td colspan="3">Predicate device
Denture 3D+</td><td colspan="3">New device:
NextDent Base</td></tr>
<tr><td></td><td>Brand</td><td>Type</td><td>Software</td><td>Brand</td><td>Type</td><td>Software</td></tr>
<tr><td>Design:</td><td colspan="6"></td></tr>
<tr><td>Printer</td><td>3D Systems</td><td>NextDent 5100 Figure 4®</td><td>3D Sprint</td><td>3D Systems</td><td>NextDent 5100 Figure 4®</td><td>3D Sprint</td></tr>
<tr><td>Post-Curing:</td><td colspan="6"></td></tr>
<tr><td>Post-cure unit</td><td>NextDent ™</td><td>LC-3DPrint Box</td><td>n.a.</td><td>NextDent™</td><td>LC-3DPrint Box</td><td>n.a.</td></tr>
</table>
</td></tr>
<tr><td>VIII. SUMMARY OF TESTING [PERFORMANCE DATA]</td><td>NextDent Base is tested for mechanical characteristics as part of the product specification. The most applicable standard for mechanical characteristics determination of denture bases is ISO 20795-1:2013 Dentistry – Base polymers – Part 1 Denture base polymers.</td></tr>
<tr><td>Biocompatibility Testing:</td><td>According to both ISO 7405:2018 and ISO 10993-1: 2018 NextDent Base is considered a surface device, in contact with intact oral mucosa, permanent (> 30 days), repeated use.

The ISO 10993-1:2018 standard, including parts 3, 5, 10, 12, 17, 18 and 23 was followed and the following applicable biological safety hazard endpoints were addressed:

Chemical characterization
Cytotoxicity
Acute systemic toxicity
Subacute/sub chronic toxicity
Irritation or intracutaneous reactivity
Sensitization
Genotoxicity

In addition, the following risks were considered based on a risk assessment, taking into account the specific nature and duration of exposure to the device

Material mediated pyrogenicity
Chronic toxicity
Presence of phthalates

In addition, ISO 10993-17 and -18 and ISO/TS 21726 were followed to identify and quantitate the extractables and/or leachables that may be released from the test article to assess the toxicological safety.</td></tr>
</table>

	NextDent Base is compliant to the applicable requirements defined in ISO 10993 including parts 1, 3, 5, 10, 12, 17, 18 and 23, ISO 7405 and ISO/TS 21726 for permanent medical devices and therefore biocompatible.

Bench Testing	NextDent Base is tested according to the methods in the industry standard ISO 20795-1:2013 Dentistry – Base polymers – Part 1 Denture base polymers. NextDent Base is compliant to the requirements defined in ISO 20795-2:2013 for Type 4 light activated material except for ultimate flexural strength, flexural modulus and water solubility. Comparative testing showed that elasticity and impact resistance properties are substantially equivalent to the predicate. NextDent Base is regarding water solubility compliant to requirements defined in ISO 20795-1:2013 for type 2 autopolymerizable materials. The following bench tests are conducted on NextDent Base: • Surface characteristics • Polishability • Color • Color stability • Translucency • Freedom from porosity • Ultimate flexural strength • Flexural modulus • Charpy impact strength • Bonding to synthetic polymer teeth • Sorption • Solubility • Dynamic fatigue • Fracture work The mechanical performance of NextDent Base printed on the NextDent 5100 printer is verified confirming its sufficient repeatability and robustness regarding print orientation, placement, and resin reuse.
Reprocessing, Sterility and Shelf-Life Testing	The device is provided non-sterile. From the Shelf-life testing, NextDent Base has a shelf life of two years.

IX. CONCLUSIONS	NextDent Base and the predicate have the same intended use and similar technological characteristics. The results of the performed tests show that NextDent Base meets the applicable requirements of ISO 20795-1:2013

	Dentistry – Base polymers – Part 1 Denture base polymers and confirm that the device performs similarly to the predicate device. It is therefore concluded that NextDent Base performs as intended and is substantially equivalent to the predicate device.