October 21, 2022

Vertex-Dental BV
℅ Patsy Trisler
Consultant
Qserve Group US Inc.
7949 Beaumont Green East Drive
Indianapolis, Indiana 46250

Re: K221022
Trade/Device Name: NextDent Ortho Flex
Regulatory Class: Unclassified
Product Code: MQC, KMY
Dated: July 22, 2022
Received: July 22, 2022

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 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)*
K221022

Device Name
NextDent Ortho Flex

Indications for Use *(Describe)*
NextDent Ortho Flex is a 3D print resin intended for the manufacturing of 3D printed dental splints and retainers. To retain the regulated dentition.

NextDent Ortho Flex 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.

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."

K221022

Section 5.0

510(k) SUMMARY— NextDent Ortho Flex

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 21, 2022

II. DEVICE		
Device Trade Name:	NextDent Ortho Flex	
Common Name(s):	Splint, retainer	
Classification Name	Mouthguard, prescription	Positioner, Tooth, Preformed
Product Codes	MQC	KMY
Regulatory Class	Unclassified (pre-amendment)	Class 1
Classification Regulation	N.a.	21 CFR 872.5525

III. PREDICATE DEVICE(s)	Nightguard Flex, K212448 (Primary predicate)

IV. DEVICE DESCRIPTION	
Device Identification:	Light-Cure Resin, provided in a container.
Device Characteristics:	NextDent Ortho Flex is a dimethacrylic based light-cure resin with pigments, polymerized via photo initiators in a 3D printer setting for fabrication of splints and retainers for long term repeated use.
Environment of Use:	• Healthcare facility/hospital • Dental (technical) laboratory.
Summary (Description) of Device:	Fabrication of splints and retainers with NextDent Ortho Flex requires a computer-aided and manufacturing (CAD/CAM) system that includes the following additive printer and post-cure unit:

<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>

Printer and resin must be optimized to each other in order to get complete and precise printed 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 Ortho Flex 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>dimethacrylate-based resins with photo-initiator and pigments.</td></tr>
</table>

V. INTENDED USE / INDICATIONS FOR USE	NextDent Ortho Flex is a 3D print resin intended for the manufacturing of 3D printed dental splints and retainers. To retain the regulated dentition. NextDent Ortho Flex is intended exclusively for professional dental work.

VI. TECHNOLOGICAL CHARACTERISTICS	NextDent Ortho Flex 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: **INTENDED USE:**	Both NextDent Ortho Flex and the predicate device are indicated to retain the regulated dentition. Both devices are intended exclusively for professional dental work.

TECHNOLOGICAL CHARACTERISTICS:

Both NextDent Ortho Flex and the predicate device have the following similar characteristics:

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

Technological characteristics	Predicate device NightGuard Flex*			New device: NextDent Ortho Flex		
	Brand	Type	Software	Brand	Type	Software
Design:						
Printer	SprintRay	Pro Printer	RayWare	3D Systems	NextDent 5100 Figure 4®	3D Sprint
Post-Curing:						
Post-cure unit	SprintRay	ProCure	n.a.	NextDent™	LC-3DPrint Box	n.a.

VIII. SUMMARY OF TESTING [PERFORMANCE DATA]

NextDent Ortho Flex is tested for mechanical characteristics as part of the product specification. The most applicable standard for mechanical characteristics determination of splints and retainers is ISO 20795-2:2013 Dentistry – Base polymers – Part 2: Orthodontic base polymers.

NextDent Ortho Flex complies to the product specifications.

Biocompatibility Testing:

According to ISO 7405:2018 NextDent Ortho Flex is considered a surface device, not in contact with oral mucosa, permanent (> 30 days), repeated use.
According to ISO 10993-1:2018 NextDent Ortho Flex is considered a surface device in contact with mucosal membrane, permanent (>30 days), repeated use.

The ISO 10993-1:2018 standard, including parts 3, 5, 10, 11, 12, 17 and 18 was followed and the following applicable biological safety aspects have been addressed:

- Cytotoxicity
- Sensitization
- Irritation or intra cutaneous reactivity
- Subacute/sub chronic systemic toxicity
- Genotoxicity

NextDent Ortho Flex is compliant to the applicable requirements defined in ISO 10993 including parts 1, 3, 5, 10, 11, 12, 17 and 18 and ISO/TS 21726 for permanent medical devices and therefore biocompatible.

Bench Testing	NextDent Ortho Flex is tested for conformity with the industry standard ISO 20795-2:2013 Dentistry – Base polymers – Part 2: Orthodontic base polymers. NextDent Ortho Flex is compliant to the applicable requirements defined in ISO 20795-2:2013 for Type 2 light-activated material. The following bench tests are conducted on NextDent Ortho Flex: • Curing • Color • Porosity • Ultimate flexural strength • Flexural modulus • Maximum stress intensity factor • Fracture work • Charpy impact strength • Sorption • Solubility There is no influence to be expected of re-use, print orientation and print placement on the final device for NextDent Ortho Flex when printed on the NextDent5100 3Dprinter. Difference between printer, difference between design, low and high temperature and or humidity are meeting the requirements of the final device made from NextDent Ortho Flex on the NextDent5100 3Dprinter.
Reprocessing, Sterility and Shelf-Life Testing	The device is provided non-sterile. From the Shelf life testing, NextDent Ortho Flex has a shelf life of 18 months.

IX. CONCLUSIONS	NextDent Ortho Flex and the predicate have the same intended use and similar technological characteristics. The results of the performed tests show that NextDent Ortho Flex meets the applicable requirements mentioned in the applicable standards and confirm that the device performs similarly to the predicate device. It is therefore concluded that NextDent Ortho Flex performs as intended and is substantially equivalent to the predicate device.