September 4, 2024

Vertex-Dental B.V.
Bart Romanus
Director Regulatory Affairs
Centurionbaan 190
Soesterberg, 3769AV
Netherlands

Re: K241071
Trade/Device Name: NextDent Jet Denture Base; NextDent Jet Denture Teeth
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI, EBG, PZY
Dated: April 19, 2024
Received: April 19, 2024

Dear Bart Romanus:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., RAC, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241071

Device Name

NextDent Jet Denture Base; NextDent Jet Denture Teeth

Indications for Use *(Describe)*

NextDent Jet Denture Base is a light curing resin intended for 3D printing of a full or partial denture base to form a denture. The product, when used in combination with NextDent Jet Denture Teeth can be used for 3D printing a removable full or partial denture.
For dental professional use only.

NextDent Jet Denture Teeth is a light curing resin intended for the 3D printing of artificial teeth to form a denture, temporary crowns or bridges. The product, when used in combination with NextDent Jet Denture Base can be used for 3D printing a removeable full or partial denture.
For dental professional use only.

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.

510(k) SUMMARY– NextDent Jet Denture - K241071

I. SUBMITTER	
Submitter Name:	Vertex-Dental B.V.
Submitter Address:	Centurionbaan 190 3769 AV, Soesterberg, The Netherlands
Contact Person: Telephone #:	B. Romanus +32 470 18 84 22
Date:	April 19th, 2024

II. DEVICE	
Device Trade Name:	NextDent Jet Denture Base, NextDent Jet Denture Teeth
Classification Name	Resin, denture, relining, repairing, rebasing Crown and Bridge, Temporary, Resin; Additively Manufactured, Preformed, Resin Denture Tooth
Product Codes	EBI, EBG, PZY
Regulatory Class	Class 2
Classification Regulation	21 CFR 872.3760 21 CFR 872.3770 21 CFR 872.3590

III. PREDICATE DEVICE(s)	NextDent Base, K231388 Saremco Print CROWNTEC, K213343

IV. DEVICE DESCRIPTION	
Device Identification:	Light-Curable Resin
Device Characteristics:	NextDent Jet Denture resins are pre-mixed combinations of acrylate-based light-cure resins with pigments, polymerized via photo initiators in a 3D printer setting for the fabrication of full or partial denture bases and artificial teeth to form a denture and for the fabrication of temporary crowns or bridges.
Environment of Use:	Dental professional use only
Summary (Description) of Device:	The resins must be used in combination with 3D Systems printers that support MultiJet Printing technology. Fit of the parts strongly depends on design and library used. Please take features like undercuts and spacers in consideration when designing the parts.

Printer	Brand	Software
Projet MJP 5600	3D Systems	3D Sprint

	Devices are produced in an automated additive manufacturing method where ultra-thin layers of photopolymer material are jetted onto a build tray. Immediately after being jetted, each photopolymer layer is cured by UV light. The process repeats layer by layer until the 3D part is complete. Upon completion the support material is removed, and the product is cleaned. When printing a denture base, bonding of artificial teeth to the denture base is possible to form a denture. The bonding agent instructions should be followed. Printed parts are finished using conventional dental methods and instruments.
Materials of Use:	Combination of acrylate-based resins with photo initiator and pigments

V. INTENDED USE / INDICATIONS FOR USE	NextDent Jet Denture is a family of acrylic monomer resins used for the fabrication of dental appliances such as removable full and partial dentures, denture bases, artificial teeth, temporary crowns, or bridges. NextDent Jet Denture Base is a light curing resin intended for 3D printing of a full or partial denture base to form a denture. The product, when used in combination with NextDent Jet Denture Teeth can be used for 3D printing a removable full or partial denture. NextDent Jet Denture Teeth is a light curing resin intended for the 3D printing of artificial teeth to form a denture, temporary crowns or bridges. The product, when used in combination with NextDent Jet Denture Base can be used for 3D printing a removeable full or partial denture. Both materials are for dental professional use only.

VI. TECHNOLOGICAL CHARACTERISTICS	NextDent Jet Denture resins are a combination of acrylate-based UV light curable resins with pigments and polymerized via with photo initiators in an automated additive manufacturing 3D printer setting.

VII. COMPARISON TO THE PREDICATE DEVICE: **INTENDED USE:**	Both NextDent Jet Denture Base and the primary predicate device (K231388) are resins intended for the manufacturing of 3D printed full and partial removable denture base to form a denture. Both NextDent Jet Denture Teeth and the secondary predicate device (K213343) are resins intended for the manufacturing of 3D printed artificial teeth to form a denture and temporary crowns or bridges. All devices are intended exclusively for professional dental work.

TECHNOLOGICAL CHARACTERISTICS:	Both NextDent Jet Denture resins and the predicate devices have the following similar characteristics: • Pre-mixed combination of acrylate-based resin with photo-initiator and pigments • Polymerization by UV light • Automated printing of resin with a 3D printer and software in multiple layers, each light-cured before adding next layer • Printed parts are finished using conventional dental methods and instruments.
VIII. SUMMARY OF TESTING [PERFORMANCE DATA]	NextDent Jet Denture resins are tested for mechanical characteristics as part of the product specifications. The most applicable standard for mechanical characteristics determination for denture bases is ISO 20795-1:2013 Dentistry – Base polymers – Part 1 Denture base polymers and for crown and bridges ISO 10477:2020 Dentistry. Polymer-based crown and veneering materials.
Biocompatibility Testing:	According to both ISO 7405:2018 and ISO 10993-1: 2018 NextDent Jet Denture resins are considered a surface device, in contact with intact mucosal membrane, permanent (> 30 days), repeated use. NextDent Jet Denture resins are 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 Jet Denture Base is tested according to the relevant methods in the standard ISO 20795-1:2013 Dentistry – Base polymers – Part 1 Denture base polymers. NextDent Jet Denture Base is compliant to the requirements defined in ISO 20795-1:2013 for Type 4 light activated material except for ultimate flexural strength, flexural modulus, water sorption and solubility. Improved impact resistance is not claimed for the device. The following bench tests are conducted on NextDent Jet Denture Base: • Surface characteristics • Polishability • Color • Color stability • Translucency • Freedom from porosity • Ultimate flexural strength • Flexural modulus • Maximum stress intensity factor

	• Total fracture work • Bonding to synthetic polymer teeth (ISO 22112) • Sorption and Solubility • Dynamic Fatigue testing • Charpy impact strength (ISO 179-1) NextDent Jet Denture Teeth is tested according to the relevant methods and meets the relevant requirements in ISO 10477 for Type 2, Class 2: polymer-based crown and veneering materials that contain a photo-polymerization initiator. The following bench tests are conducted on NextDent Jet Denture Teeth: • Flexural strength • Water sorption • Sorption and Solubility • Color stability • Shade consistency • Surface characteristics • Polishability The mechanical performance of NextDent Jet Denture resins printed on the Projet MJP 5600 printer is verified confirming its sufficient repeatability and robustness regarding print orientation and placement.
Reprocessing, Sterility and Shelf-Life Testing	The device is provided non-sterile. NextDent Jet Denture resins have a shelf life of two years.

IX. CONCLUSIONS	NextDent Jet Denture resins and the predicate devices have similar intended use and technological characteristics. The results of the performed tests show that: • NextDent Jet Denture 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 primary predicate device. • NextDent Jet Denture Teeth meets the relevant requirements of ISO 10477:2020 Dentistry. Polymer-based crown and veneering materials and performs similarly to the secondary predicate device. It is therefore concluded that NextDent Jet Denture resins perform as intended and are substantially equivalent to the predicate devices.