November 16, 2020

Detax GmbH & Co. KG
% Jan-Paul Van Loon
Consultant
Qserve Consultancy BV.
Utrechtseweg 310 - Bldg B42
Arnhem, Gelderland 6812 AR
Netherlands

Re: K200461
Trade/Device Name: Freeprint denture
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: October 19, 2020
Received: October 20, 2020

Dear Jan-Paul Van Loon:

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 “Nandu” Nandkumar, Ph. D.
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)*
K200461

Device Name
FREEPRINT denture

Indications for Use *(Describe)*

FREEPRINT denture is a light-cured resin indicated for the fabrication of all types of denture bases, for instance full and partial removable dentures.
FREEPRINT denture is intended for continuous use in the oral environment, exclusively for professional dental work.
FREEPRINT denture can be used in combination with a stereolithographic 3D printer using a 385nm light source. A 3D-printer is not part of the device.

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.

K200461 - 510(k) Summary

I SUBMITTER

Submitter Name:	DETAX GmbH & Co.KG.
Submitter Address:	Carl-Zeiss-Stasse 4 D-76275 Ettingen Germany
Phone Number:	+49 (0)7243/510-138
Contact Person:	M. (Markus) Stratmann
Date Prepared:	February 6, 2020

II. DEVICE

Device Trade Name:	FREEPRINT denture
Common Name	Denture relining, repairing, or rebasing resin
Classification	21 CFR 872.3760
Product Code:	EBI
Review Panel:	Dental

III. PREDICATE DEVICE K162572, NextDent™ Denture/E-Denture, Vertex-Dental BV.,

IV. DEVICE DESCRIPTION

Description FREEPRINT denture is a light-cured one-component materials for the Digital Light Processing (DLP)-printing of denture base products. It is stored in 500 and 1000ml HDPE bottles. This Product is a liquid photo-curable material that is polymerized, by the photo-initiator contained in the resin. This device can be manufactured with 3D stereolithographic printer with 385nm wavelength light source. Curing in a 3D printer is related to the conditions of the printer equipment and is typically 100µm in thickness. FREEPRINT denture products are post cured with a xenon flashlight, in a nitrogen atmosphere.

Physical Description: FREEPRINT denture: dimethacrylate based resin 1-component system.
Processed (3D printed) using 385nm light source.

V. INTENDED USE / INDICATION FOR USE STATEMENT FREEPRINT denture is a light-cured resin indicated for the fabrication of all types of denture bases, for instance full and partial removable dentures.
FREEPRINT denture is intended for continuous use in the oral environment, exclusively for professional dental work.
FREEPRINT denture can be used in combination with a stereolithographic 3D printer using a 385nm light source. A 3D-printer is not part of the device.

VI. SUMMARY OF TECHNOLOGICAL CHRACHTERISTICS OF DEVICE COMPARED TO

PREDICATE DEVICES

Indications for Use and Technological Characteristics:

FREEPRINT denture has a similar Indications for Use statement as the predicate device.
The FREEPRINT denture has the following similarities in the technological characteristics to the predicate device, NextDent™ Denture/E-Denture, Vertex-Dental BV (K162572):

- Same type of materials (chemical composition) that form the basis for the device used
- Same technology, however different wavelength used for polymerization (Curing) method
- Similar mechanical and physical properties of processed device.

Summary of Performance Data and Design Controls:

Bench testing was carried out on the following characteristics:

- Printers validation

Four printers are validated for processing (3D printing) using FREEPRINT denture. Additional printers post-510(k)-clearance will be added to the labelling by means of the Quality Systems and within the validation plan presented in this 510(k).

Referenced Standards and Performance Testing:
Performance testing confirmed the FREEPRINT denture demonstrated performance to the acceptance criteria referred to ISO 20795-1.
The composition of FREEPRINT denture exhibits sufficient strengths and performances in all intraoral conditions and will sufficiently resist compressive & tensile loads, hardness, water sorption and solubility.

Biocompatibility testing:
FREEPRINT denture was tested with respect to biocompatibility according to ISO 10993-3, ISO 10993-5, ISO 10993-10, ISO 10993-11 and ISO 10993-17, taking ISO 7405 into account. The results showed that the insolubility is in compliance with the requirements of the standard. There is no evidence that hazardous effects will arise by leachable ingredients/contaminants.

Clinical Tests
No clinical tests were performed with FREEPRINT denture

Sterility and Shelf-Life Testing:

Sterilization
FREEPRINT denture is provided non-sterile.

From the Shelf-life testing, FREEPRINT denture has a shelf life of two years.

VIII. CONCLUSION OF SUBSTANTIAL

FREEPRINT denture and the predicate have the same intended use and similar technological characteristics.

EQUIVALENCE

The results of the performed tests show that FREEPRINT 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 FREEPRINT denture is substantially equivalent to the predicate device.