November 19, 2020

Dreve Dentamid GmbH
% Nevine Erian
Regulatory Consultant
BQC Consulting LLC
24341 Barbados Dr.
Dana Point, California 92629

Re: K200580
Trade/Device Name: FotoDent denture
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture relining, repairing, or rebasing resin
Regulatory Class: Class II
Product Code: EBI
Dated: November 10, 2020
Received: November 17, 2020

Dear Nevine Erian:

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)*
K200580

Device Name

**FotoDent® denture**

Indications for Use *(Describe)*

FotoDent® denture is a light curing resin intended for manufacturing of full and partial removable dentures.

Type of Use *(Select one or both, as applicable)*

**X** 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# K200580
# 510(k) Summary


**Submitter** **Dreve Dentamid GmbH**
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**Date Prepared** March 25, 2020

- **Trade/Device Name** FotoDent® denture
- **Common Name** Denture Material
- **Classification Name** Resin, Denture, Relining, Repairing, Rebasing
- **Regulation Number** 21 CFR 872.3760
- **Product Code** EBI

**Predicate Devices**

DENTCA Denture Base II (DENTCA, Inc.) – K162044 – ***Primary Predicate***

## Device Description

FotoDent® denture is a light curable resin for 3D printing of full and partial dentures.

## Statement of Intended Use

FotoDent® denture is a methacrylate-based material for denture fabrication.

## Statement of Indication for Use

FotoDent® denture is a light curing resin intended for manufacturing of full and partial removable dentures.

## Material Composition

FotoDent® denture is a methacrylate-based resin.

## Technological Characteristics

FotoDent® denture is a light-curing resin for 3D printing.

## Non-Clinical Performance Testing

FotoDent® denture was tested and met the applicable requirements of the following FDA Recognized Consensus standard:

- ISO 20795-1:2013 – Dentistry – Base polymers – Part 1: Denture base polymers
- ISO 7491:2000 – Dentistry – Dental materials – Determination of colour stability

Bench test results allowed us to conclude that FotoDent® denture meets its intended use.

## Biocompatibility

FotoDent® denture meets the biocompatibility requirements of the following standards:

- ISO 10993-1:2009 – Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 7405:2008 Dentistry – Evaluation of Biocompatibility of Medical Devices Used in Dentistry

## Clinical Performance Data

Not applicable. No human clinical testing was performed to support the substantial equivalence of FotoDent® denture.

## Substantial Equivalence

The technical characteristics of FotoDent® denture is substantially equivalent to the predicate device.

### *Material*

FotoDent® denture is a resin-based material as the predicate device.

### *Physical Properties*

FotoDent® denture has similar physical properties as the predicate devices.

**Technical Comparison of FotoDent® denture to Predicate Devices**

| *Attribute* | FotoDent® denture | DENTCA Denture Base II |
|---|---|---|
| **Indications** | | |
| **Manufacturing of full dentures** | Yes | Yes |
| **Manufacturing of partial dentures** | Yes | Yes |
| **Physical Property** | | |
| **Type 4 (light-activated) acrylic resin per ISO 20795-1** | Yes | Yes |
| **Before Curing (liquid state)** | | |
| **Viscosity** | 400 < X < 600 cps | 1000 < X <2000 cps |
| **Density** | 1.05 – 1.15 g/cm³ | 1.05 < X <1.2 g/cm3 |
| **After Curing (solid state)** | | |
| **Density** | 1.05 – 1.15 g/cm³ | 1.15 < X <1.25 g/cm3 |
| **Flexural Strength** | >80 MPa | >65 MPa |
| **Flexural Modulus** | >2000 MPa | >2000 MPa |
| **Material Type** | Resin based | Resin based |
| **Technical Attributes** | | |

| *Attribute* | FotoDent® denture | DENTCA Denture Base II |
|---|---|---|
| **Chemical Characterization** | Methacrylate/acrylate resins with photo-initiators, pigments and additives | Methacrylate/acrylate resins with photo-initiators, pigments and additives |
| **Shelf Life** | 2 years | 2 years |
| **Storage** | 18 - 28°C<br>Do not expose to direct sunlight | 15-25°C<br>Do not expose to direct sunlight |
| **Physical Configuration** | Supplied in liquid form | Supplied in liquid form |
| **Shades** | 2 shades of pink | 4 shades of pink |
| **Application** | 3D Printing | 3D Printing |
| **Fabrication Type** | Automated 3D printing of resin in multiple layers, each layer light-cured before adding next layer | Automated 3D printing of resin in multiple layers, each layer light-cured before adding next layer |
| **Polymerization (Curing Method)** | Light-curing resin | Light-curing resin |
| **Post Curing** | light-curing unit | light-curing unit |
| **Teeth Assembly** | Bonding | Bonding |
| **Sterile** | No | No |
| **Single Use** | No | No |
| **Environment of Use** | Dental Laboratory | Dental Laboratory |

The differences in physical properties between FotoDent denture and the predicate device does not impact safety and effectiveness, as the finished clinical product is a custom-fitted denture base regardless of the material variation.

**Conclusion**

Information provided in this application demonstrates that FotoDent® denture is substantially equivalent to the predicate device. FotoDent® denture has same indications for use, similar material composition, similar physical properties and technological characteristics as the DENTCA Denture Base II products.