March 23, 2021

DIO Corporation
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K210828
Trade/Device Name: DIOnavi-Denture02
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture relining, repairing, or rebasing resin
Regulatory Class: Class II
Product Code: EBI
Dated: March 7, 2021
Received: March 19, 2021

Dear Dave Yungvirt:

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,

Michael E. Adjodha, M.ChE.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210828

Device Name
DIOnavi-Denture02

Indications for Use *(Describe)*
DIOnavi-Denture02 is a light-curable resin indicated for fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional heat-curable and auto polymerizing resins. Fabrication of dental prosthetics with DIOnavi-Denture02 requires a computer-aided design and manufacturing (CAD/CAM) system that includes the following components: digital denture base files based on a digital impression, a digital light processing (DLP) printer, and curing light equipment.

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.

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K210828

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirement of 21 CFR part 807.92

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Device Information:

Trade Name: DIOnavi-Denture02
Common Name: Light-cured denture resin
Classification Name: Denture relining, repairing, or rebasing resin
Product Code: EBI
Panel: Dental
Regulation Number: 21 CFR 872.3760
Device Class: Class II
Date prepared: March. 17. 2021

General Description

DIOnavi-Denture02 is a photo-cured resin intended to fabricate full and partial removable dentures in a CAD/CAM additive printing process. The material is an alternative to traditional heat cured and auto polymerization resins. It is denture base resins, Photo-cured product family comprises a family of dimethacrylate resins. The dimethacrylate resin is polymerized via photo initiators in a 3D printer. The color of the denture is determined by the addition of pigments. The material is used in a 3D printer, which prints the shape determined by a 3D drawing. After printing, the printed product is placed in a UV-light curing box for final polymerization. 3D printer and UV-light curing box is not included with the device.

The denture fabrication process begins with a traditional impression or optical impression of the oral region in the dentist office. This impression is sent to a dental lab. The denture base is then made layer-by-layer in a DLP (digital light processing) printer. After attachment of preformed plastic teeth, the denture is cured in a light chamber, and, lastly, sent back to the dentist for try-in and final adjustment.

Indication For Use

DIOnavi-Denture02 is a light-curable resin indicated for fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional heat-curable and auto polymerizing resins. Fabrication of dental prosthetics with DIOnavi-Denture02 requires a computer-aided design and manufacturing (CAD/CAM) system that includes the following components: digital denture base files based on a digital impression, a DLP (digital light processing) printer, and curing light equipment.

Predicate devices

The subject device is substantially equivalent to the following Predicate Device:

Primary Predicate Device : DIOnavi-Denture (K193623)

Summaries of Technological Characteristics

The subject device is substantially equivalent to the currently cleared devices. They are substantially equivalent in intended use, material and connection interfaces to the implants are identical for each individual diameter and connection type. Comparison demonstrating Substantial Equivalence follows:

	Subject Device	**Primary Predicate Device**
Applicant	DIO Corporation	DIO Corporation
Trade Name	DIOnavi-Denture02	DIOnavi-Denture
510(K) No.	Not yet assigned	K193623
Regulation Name	Denture Relining, Repairing, Or Rebasing Resin	Denture Relining, Repairing, Or Rebasing Resin
Product Code	EBI	EBI
Class	Class II	Class II
Device Identification	Light-cured resin	Light-cured resin
Indications for Use	DIOnavi-Denture02 is a light-curable resin indicated for fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional heat-curable and auto polymerizing resins. Fabrication of dental prosthetics with DIOnavi-Denture02 requires a computer-aided design and manufacturing (CAD/CAM) system that includes the following components: digital denture base files based on a digital impression, a digital light processing (DLP) printer, and curing light equipment.	DIOnavi-Denture is a light-curable resin indicated for fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional heat-curable and auto polymerizing resins. Fabrication of dental prosthetics with DIOnavi-Denture requires a computer-aided design and manufacturing (CAD/CAM) system that includes the following components: digital denture base files based on a digital impression, a digital light processing(DLP) printer, and curing light equipment.
Chemical composition	Dimethacrylate-based resins with photo-initiator, and pigments.	Dimethacrylate-based resins with photo-initiator, and pigments.
Chemical formulation	Pre-mixed liquid resin provided in a container	Pre-mixed liquid resin provided in a container
Polymerization (Curing) Method	Visible light	Visible light
Fabrication of Denture Base	Automated 3D printing of resin in multiple layers, each light-cured before adding next layer, with post curing in light chamber	Automated 3D printing of resin in multiple layers, each light-cured before adding next layer, with post curing in light chamber
Post Curing	Visible light-curing unit	Visible light-curing unit
Product State	Pre-mixed resin (liquid)	Pre-mixed resin (liquid)
Teeth Assemble	Bonding	Bonding
Sterilization	Non-sterile	Non-sterile
Shelf-life	2 years	2 years
Device Characteristics	Automated 3D printing of resin in multiple layers, each light-cured before adding next layer, with post curing in light chamber.	Automated 3D printing of resin in multiple layers, each light-cured before adding next layer, with post curing in light chamber.
Substantial Equivalence Discussion	The indications for use and the technological characteristics are the same between the subject device and the predicate device. The subject device and the predicate device use similar technologies to make the final dentures and base plates, including the type of printer	

	used. Both devices use digital light processing(DLP) printer. The physical properties and the steps in the process are also similar. The indications for Use Statement is exactly the same as the predicate device. They using a same type of raw material as Dimethacrylate-based resin. There might be differences in formulation, however, we have performed biocompatibility tests in accordance with ISO 10993 and performance tests in accordance with ISO 20795-1. All of the test results met the criteria and demonstrated that this difference would not raise a question in substantial equivalence and the subject device would perform as well as the predicate devices. Based on the information submitted herein, we conclude that the subject device is substantially equivalent to the predicate device.

Non-clinical Testing

Performance tests in accordance with ISO 20795-1 including visual inspection, Weight, package inspection, dimensions, surface characteristics, shape capability, translucency, color, color stability, flexural strength and flexural modulus, water sorption, water solubility and form porosity test.
The subject device used for the preparation of the test specimen was manufactured using a digital light processing (DLP) 3D printer. The following printer(s) is validated for processing (3D printing) using DIOnavi-Denture02.

- Manufacturer : DIO Corporation
- Name of printer : DIO PROBO
- Model number : PROBO

Additional printers post-510(k) clearance will be added to the labelling by means of the Quality Systems and within the company's validation plan.

The results of the non-clinical testing demonstrate that the results have met the criteria of the standards, and the subject device is substantially equivalent to the predicate device.

Shelf Life Testing

Subject device has a shelf life of 2 years.
The shelf-life testing has been conducted with the bench tests from ISO 20795-1.

Biocompatibility

Biocompatibility Tests in accordance with "*Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*Guidance for Industry and Food and Drug Administration Staff*SEPTEMBER 2020"*

Subject device is considered a surface device, in contact with the mucosal membrane, for > 30 days.
The ISO 10993-1 standard was followed and the following biological safety aspects have been addressed:
Cytotoxicity in accordance with ISO 10993-5
Sensitization in accordance with ISO 10993-10
Irritation reactivity test in accordance with ISO 10993-10
Genotoxicity test in accordance with ISO 10993-3
Sub-acute toxicity in accordance with ISO 10993-11
Material-mediated pyrogenicity in accordance with ISO 10993-11

Summary of clinical testing

No clinical testing was performed for this submission.

Conclusions

The test results of non-clinical tests performed on the subject device supported that it is substantially equivalent to the predicate devices despite the differences. Based on the information provided in this premarket notification, DIO Corporation concludes that the DIOnavi-Denture02 is substantially equivalent to the predicate device as described herein in.