February 23, 2024

Ivoclar Vivadent, Inc
Anderjeet Gulati
Sr Manager of QA & Regulatory Affairs
175 Pineview Drive
Amherst, New York 14228

Re: K233995
Trade/Device Name: Ivotion Base Print
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: December 5, 2023
Received: December 18, 2023

Dear Anderjeet Gulati:

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.

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,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
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OHT1: Office of Ophthalmic, Anesthesia,
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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)*

K233995

Device Name

Ivotion Base Print

Indications for Use *(Describe)*

Complete edentulism

Areas of application:
Denture bases in removable complete denture prosthetics

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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510(K) SUMMARY

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Date Prepared: February 5, 2024

Proprietary Name: **Ivotion® Base Print**

Classification Name: Resin, Denture, Relining, Repairing, Rebasing (872.3760)
(Classification Code EBI)

Common Name: Denture Material

Predicate Device: FotoDent denture (K200580) by Dreve Dentamid GmbH, Germany

Reference Device: NexDent Denture/E-Denture (K162572) by Vertex-Dental BV

Device Description: **Ivotion® Base Print** is a light-curing resin material for stereolithography 3D printing. It is suitable for the fabrication of permanent denture bases in removable complete denture prosthetics. The material can be processed with approved 3D printing system. The dental professional starts with preparation of the printing procedure, cleaning, post-curing, finishing and polishing. A denture fabricated with Ivotion Base Print can be repaired and relined using a conventional self-curing denture base material.

Indications for Use:

Complete edentulism

Areas of application:

Denture Bases in removable complete denture prosthetics

Comparison to Predicate: The primary predicate device to which Ivotion Base Print has been compared is Dreve Dentamid GmbH- FotoDent denture (K200580).

	Predicate Device:	Proposed Device:	Deviation	
Device	**Dreve Dentamid GmbH: FotoDent denture (K200580)**	**Ivoclar Vivadent AG: Ivotion Base Print**	**Yes**	**No**
Indications for Use	**Indications for Use**: FotoDent denture is a light curing resin intended for manufacturing of full and partial removable dentures	**Indications for Use**: Complete edentulism *Areas of application:* Denture bases in removable complete denture prosthetics	☒	☐
Precaution Measures/ Contraindications/ Processing restrictions/ Side effects	**Contraindications**: FotoDent denture is contraindicated for individuals with known allergy to methacrylates and acrylates.	**Contraindications:** The use of the product is contraindicated if the patient is known to be allergic to any of its ingredients.	☐	☒
Summary of Indications, Precaution Measures/ Contraindications/ Processing restrictions/ Side effects	The new device is indicated for removable complete dentures in contrast to the predicate, which is used for full and partial removable dentures. The Contraindications are the same.			
Working Principle	Device description: FotoDent denture is a light curable resin for 3D printing of full and partial dentures. Technological characteristics: FotoDent denture is a light-curing resin for 3D printing	Ivotion Base Print is a light-curing resin material for stereolithography 3D printing. It is suitable for the fabrication of permanent denture bases in removable complete denture prosthetics. The material can be processed with approved 3D printing systems.	☐	☒
Summary of Working Principle	The working principles for the predicate and new device are basically the same. Both devices are used to 3D print removable dentures.			
Delivery forms/dosage	Supplied in liquid form, 1 kg	Bottle of liquid, 1000ml	☐	☒
Summary of Delivery forms/dosage	The new device is available in less shades and translucencies compared to the predicate device. The new device is available with a color gradient ("Multi") which is a new feature compared to the predicate.			
Storage Conditions	2 years at 18-28 °C	24 months at 2-28 °C / 36-82 °F	☒	☐
Summary of Storage Conditions	No difference in shelf life. Storage conditions differ between the 2 devices.			
Principles of Operation	**Processing:** - Preparation for printing procedure - Cleaning - Post curing - Temper (Finish)	**Step-by-step:** - Preparation of the printing procedure - Cleaning - Post-curing - Finishing - Polishing - Repair/Relining	☒	☐
Summary Principles of operation	The principles of operation are basically the same. Both devices are used to 3D print dentures (full or partial).			

Summary of Chemical Composition	Biocompatibility has been thoroughly assessed for Ivotion Base Print, see Biocompatibility Assessment for Ivotion Base Print.						
Finished Device Specification	*ISO 20795-1:2013 – Dentistry – Base polymers – Part 1: Denture base polymers*			*ISO 20795-1:2013 – Dentistry – Base polymers – Part 1 Denture base polymers*		☐	☒
Device Specification	Performance	Value	Unit	Value	Unit		
	Specification Flexural strength	> 80 (predicate device)	MPa	≥ 65	MPa	☒	☐
	Flexural modulus	> 2000 (predicate device)	MPa	≥ 2000	MPa	☐	☒
	Water absorption	No values available for predicate or reference device	---	≤ 32	µg/mm3	☒	☐
	Water solubilty	Reference device: water sorption meets the requirement of Type 2 materials acc to ISO 20795-1.	---	≤ 8.0	µg/mm3	☒	☐
	MMA residual monomer content	No values available for predicate or reference device	---	≤ 2.2	%	☒	☐
Summary of Finished Device Specification	Currently, there is no ISO standard that defines the physical requirements for denture base materials processed with 3D printing systems. The product complies with the requirements of ISO 20795-1 for photo-polymerizable denture base resins. The water solubility value fulfils the specification defined in ISO 20795-1 for self-curing materials. The FDA Guidance is fulfilled by Ivotion Base Print.						
Sterilization	Not applicable. No sterilization recommendation.			Not applicable. No sterilization recommendation.		☐	☒
Single use	Consumable material			Consumable material		☐	☒
Summary of Performance Specification	The performance is compliant with the requirements of ISO 20795-1 and substantially equivalent for both devices.						

Substantial Equivalence to the predicate:

The working principle is the same for both devices. There is no detailed information regarding the chemical composition available for the predicate device. Therefore, detailed biocompatibility testing has been assessed for Ivotion Base Print. The device performance is considered to be equivalent for the new and the predicate device.

Therefore, **Ivotion Base Print** is substantially equivalent to the predicate device.

Differences:

Indication differs in that it has been reduced from full and partial for the predicate to only be for complete dentures for Ivotion Base Print.

The temperature range for storage conditions differ. The storage conditions are a result of the storage stability testing performed.

There are some deviations in the principles of operation, but they are basically the same. The new device includes the additional steps of finishing, polishing and repair/relining in the principles of operation.

There is no detailed composition available for the predicate device, but it is known that FotoDent denture is a light-curing methacrylate-based material for denture fabrication. The ingredients that have not been used before in Ivoclar Vivadent AG's products have a CAS number identified and biocompatibility has been thoroughly assessed for Ivotion base Print.

There is a difference between the flexural strength values of the predicate and the new device, but the other device specifications differences were a result of no values available for the predicate. The device specifications- flexural strength, flexural modulus, water absorption and MMA residual monomer content are compliant to the requirements defined in ISO 20795-1 Type 4 (light activated).

Non-clinical performance testing:

Bench testing was performed to test the physical properties included in the Finished Device Specification for the subject device including: flexural strength, flexural modulus, water absorption, water solubility, and MMA residual monomer content according to EN ISO 20795-1:2013- Dentistry- Base polymers- Part 1 Denture base polymers (ISO 207951:2013).

Biocompatibility:

The subject device was also evaluated for Biocompatibility according to ISO 10993, ISO 7405, ISO 21726:2019 and ISO 14971:2019. The biological evaluation was performed based on toxicological data on relevant component materials / compounds, information on prior use of relevant component materials / compounds, data from biological tests, data on the history of clinical use or human exposure. Based on the information included in the biological evaluation report it can be concluded that the product under evaluation is acceptable in relation to its clinical benefit. The product under assessment does not release leachable substances in cytotoxic concentrations; The product is considered to have no sensitizing properties; the product is not irritative to the oral mucosa; The product does not contain biologically derived materials. Consequently, no material mediated pyrogenicity is expected; The product shows no acute systemic toxic characteristics; The risk for sub-acute, sub-chronic or chronic systemic toxicity induced by the product under assessment is acceptable; the finished product is considered to be non-mutagenic; The novel raw materials contained in the product are considered to be non-mutagenic; and the carcinogenic risk induced by the finished product is negligible.

It can be concluded that the product does not represent a toxicological risk for the patient and the user.

Based on the toxicological evaluation of the product and the longstanding worldwide clinical use of similar materials it can be concluded that the benefits provided by the final product will exceed any potential risks produced by device materials providing that instructions for use have been followed.

Conclusion:

The new device Ivotion Base Print and the predicate device FotoDent Denture are 3D printable materials to fabricate denture bases for full (new device) or partial removable dentures (predicate device). The working principle is the same for both devices. There is no detailed information regarding the chemical composition available for the predicate device. Therefore, detailed biocompatibility testing has been assessed for Ivotion Base Print. The device performance is considered to be equivalent for the new and the predicate device.

Therefore, **Ivotion Base Print** is substantially equivalent to the predicate device.