October 30, 2025

detax GmbH
℅ Chris Brown
Manager
Aclivi, LLC
3250 Brackley Drive
Ann Arbor, Michigan 48105

Re: K252430
Trade/Device Name: Freeprint® denture flex
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: August 1, 2025
Received: August 1, 2025

Dear Chris Brown:

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.

510(k) Number *(if known)*
K252430

Device Name
Freeprint® denture flex

Indications for Use *(Describe)*
The Freeprint® denture flex is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment. The Freeprint® denture flex is indicated for the fabrication, by additive manufacturing, of dental objects such as flexible partial removable dentures.

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
Freeprint® denture flex
October 30, 2025
K252430

ADMINISTRATIVE INFORMATION

Manufacturer Name	detax GmbH Carl-Zeiss-Strasse 4 D-76275 Ettingen, Germany Telephone: +49 7243/510-138 Fax: n/a
Official Contact	Barbara Voigt, Head of Quality and Regulatory
Email:	Barbara.Voigt@detax.de

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Freeprint® denture flex
Common Name:	Resin, Denture, Relining, Repairing, Rebasing
Regulation Name:	Denture relining, repairing, or rebasing resin
Regulation Number:	21 CFR 872.3760
Device Class:	Class II
Product Code:	EBI
Review Panel:	Dental Products Panel
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

PREDICATE DEVICE INFORMATION

The Subject device is substantially equivalent in Indications for Use, and Technological Characteristics to the following legally marketed Predicate and Reference devices and leverages biocompatibility from the sponsor's legally marketed Reference device:

510(k)	Predicate Device Name (Primary)	Company Name
K200461	Freeprint® denture	detax GmbH

510(k)	Reference Device Name	Company Name
K213994	Flexible Block	Shandong Huge Dental Material Corporation
K232448	Freeprint® splintmaster	detax GmbH

INDICATIONS FOR USE

The Freeprint® denture flex is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment. The Freeprint® denture flex is indicated for the fabrication, by additive manufacturing, of dental objects such as flexible partial removable dentures.

DEVICE DESCRIPTION

Freeprint® denture flex is a light-cured, 3D printed flexible denture resin. The Subject device is used by a dental professional (dentist or dental technician) in the CAD/CAM manufacturing of patient-specific partial dentures. There are two models of the Subject device which are referred to as Freeprint® denture flex clear and Freeprint® denture flex pink-transparent. The Subject device is a viscous solution consisting of methacrylate-based resins, photo initiators and pigment and is provided in an HDPE bottle.

The Subject device resin is used within a validated manufacturing workflow to create the intended dental device. Dental devices fabricated using the Subject device are one-time use, prescription-only devices.

Non-clinical Performance Data

Non-clinical data submitted to demonstrate substantial equivalence included:

- biocompatibility testing according to ISO 10993-1
- manufacturing validation
- Material performance testing to ISO 20795-1
- Comparative performance testing
- magnetic resonance information (MRI) safety assessment

Biocompatibility

Biocompatibility testing and evaluation according to ISO 7405, ISO 10993-1, ISO 10993-3, ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-17, ISO 10993-18, ISO 10993-23, ISO/TS 21726 was performed on the K232448 Reference device and leveraged for the Subject device.

Manufacturing Validation

A manufacturing validation was performed to validate the use of the Subject device with a compatible 3D printer and post-curing device.

Mechanical Performance

Mechanical performance testing of the Subject device was performed according to ISO 20795-1. Comparative testing was performed with the K213994 to demonstrate substantial equivalence.

The results of the non-clinical testing demonstrate that the Subject device is suitable for the intended use and is the same or highly similar to the Predicate device, leveraging technology of the Reference devices.

Magnetic Resonance Imaging Safety

The Subject device was evaluated for MR Safety and is labeled as MR Safe.

No clinical or animal testing data is included in this premarket notification.

Equivalence to Marketed Devices

Provided at the end of this summary are tables comparing the Indications for Use Statements and the technological characteristics of the Subject, Predicate, and Reference devices.

Indications for Use Statement

Predicate Device K200461, Freeprint® denture

The Subject device Indications for Use Statement (IFUS) is similar to that of the K200461 Predicate device. The device name differs, but that does not impact the indications or intended use of the devices. They both indicate the devices are 3D print resin which is externally cured using different words to express the same intent. The nature of compatible printers and light sources is addressed in labeling and not an inherent or necessary part of

the IFUS and does not impact the intended use of the material to be used to fabricate denture bases. The nature of the Subject device material performance is optimized for the partial denture base use, so full dentures are not listed in the Subject device IFUS.

Reference Device K213994, Flexible Block
The Subject device IFUS is similar to that of the K213994 Reference device. The device name differs, but that does not impact the indications or intended use of the devices. The K213994 Reference device is used for both denture bases and orthodontic appliances whereas the Subject device is used for only denture bases. Both IFUS indicate similar indications and intended uses using different words to express the same intent.

Reference Device K232448, Freeprint® splintmaster
The Subject device IFUS is similar to that of the K232448 Reference device. The device name differs, but both devices are intended to fabricate dental objects by means of additive manufacturing. The K232448 Reference device is leveraged for biocompatibility as it has the same patient contact and duration and similar indications as the Subject device.

Technological Characteristics
Predicate Device K200461, Freeprint® denture
The Subject and Predicate devices are highly similar or the same in all Technological Characteristics. The intended use of the Subject device is encompassed within the intended use of the Predicate device. Minor differences in ISO 20795-1 material performance results between the Subject and Predicate devices do not impact safety or effectiveness as these differences are mitigated by comparative bench performance testing with the K213994 Reference device.

Reference Device K213994, Flexible Block
The Subject and K213994 Reference devices are highly similar in Technological Characteristics. Differences in Material Technology, Material, Polymerization Method and Manufacturing Equipment do not change the intended use of the devices to be used in the fabrication of dental objects such as removable dentures. Comparative performance testing between the Subject and K213994 Reference was performed to demonstrate substantial equivalence.

Reference Device K232448, Freeprint® splintmaster
The Subject and K232448 Reference devices are similar in Technological Characteristics. They have similar intended uses, namely fabrication of dental objects, but the specific indications for use are different. The Subject and K232448 Reference devices have the same patient contact and duration and share the same/highly similar raw materials and manufacturing process. While the K232447 Reference device material was tested to a different standard (ISO 207950-2), the Subject device was tested to the standard (ISO 20795-1) which covers the intended denture base usage. The K232448 Reference device is leveraged to support Biocompatibility of the Subject device supporting substantial equivalence.

CONCLUSION
Overall, the Indications for Use statements of the Subject device and the K200461 Predicate are similar, differing in specific wording of the device name, with the Subject device intended for a subset of indications covered by the Predicate device.

Overall, the Technological Characteristics of the Subject device are highly similar or the same as the Predicate device. Slight differences in Technological Characteristics between the Subject, Predicate and Reference devices are supported through bench performance testing.

Overall, the Subject device is substantially equivalent to the Predicate device. Minor differences are supported by technological characteristics leveraged from Reference devices and bench performance testing.

Comparison Tables

Subject Device Freeprint® denture flex detax GmbH	**Predicate Device** Freeprint® denture detax GmbH K200461	**Reference Device** Flexible Block Shandong Huge Dental Material Corporation K213994	**Reference Device** Freeprint® splintmaster detax GmbH K232448
The Freeprint® denture flex is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment. The Freeprint® denture flex is indicated for the fabrication, by additive manufacturing, of dental objects such flexible partial removable dentures.	*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 3Dprinter is not part of the device.*	*Intended for making dental plates, bite plates, frameworks, clasps, personal trays, appliances, occlusal splints and night guards.*	*FREEPRINT® splintmaster is a light-curable polymerizable resin intended to be used in conjunction with extra-oral curing light equipment. FREEPRINT® splintmaster is indicated for the fabrication, by additive manufacturing, of orthodontic and dental objects such as mouthguards, nightguards, splints, and repositioners.*

Table A. Substantial Equivalence - Indications for Use Statement

Comparison	**Subject Device** Freeprint® denture flex detax GmbH	**Predicate Device** Freeprint® denture detax GmbH K200461	**Reference Device** Flexible Block Shandong Huge Dental Material Corporation K213994	**Reference Device** Freeprint® splintmaster detax GmbH K232448
Product Code	EBI	EBI	EBI, MQC	MQC, KMY
Regulation	21 CFR 872.3760	21 CFR 872.3760	21 CFR 872.3760	Unclassified
Intended Use	Used in the fabrication of dental objects such flexible partial removable dentures.	Used in the fabrication of dental objects such full and partial removable dentures.	Used in the fabrication of orthodontic and dental objects including dentures.	Used in the fabrication of orthodontic and dental objects.
Reason for Predicate/Reference	Not Applicable	Intended use, manufacturing process	Intended use, material performance	Biocompatibility
Material Technology	3D liquid (light-cured) print resin for dental CAD/CAM	3D liquid (light-cured) print resin for dental CAD/CAM	Resin disk for dental CAD/CAM	3D liquid (light-cured) print resin for dental CAD/CAM
Material	Methacrylate resin, photo initiator	Methacrylate resin, photo initiator	Methacrylate resin	Methacrylate resin, photo initiator
Polymerization (Curing) Method	UV light, 385 nm w/post curing	UV light, 385 nm w/post curing	Pre-polymerized	UV light, 385 nm w/post curing
Prescription device	Yes	Yes	Yes	Yes
Manufacturing Equip	Validated 3D-Printer and post curing devices	Validated 3D-Printer and post curing devices	Dental Milling machine	Validated 3D-Printer and post curing devices
Performance Testing	ISO 20795-1	ISO 20795-1	ISO 20795-1	ISO 20795-2
Biocompatibility Testing	ISO 7405 ISO 10993-1 ISO 10993-3 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-17 ISO 10993-18 ISO 10993-23 ISO/TS 21726	ISO 7405 ISO 10993-3 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-17	ISO 10993-3 ISO 10993-5 ISO 10993-10 ISO 10993-11	ISO 7405 ISO 10993-1 ISO 10993-3 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-17 ISO 10993-18 ISO 10993-23 ISO/TS 21726
Biocompatibility	Yes	Yes	Yes	Yes
Sterile	No	No	No	No

Table B. Substantial Equivalence – Technological Characteristics