



November 7, 2025

Dreve Dentamid GmbH  
Anke Hüttenbrauck  
Head of Regulatory Affairs  
Max-Planck-Str. 31  
Unna, NRW 59423  
GERMANY

Re: K250739

Trade/Device Name: Primeprint Direct Aligner  
Regulation Number: 21 CFR 872.5470  
Regulation Name: Orthodontic Plastic Bracket  
Regulatory Class: Class II  
Product Code: NXC  
Dated: October 9, 2025  
Received: October 9, 2025

Dear Anke Hüttenbrauck:

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](mailto: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

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

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K250739

?

Please provide the device trade name(s).

?

Primeprint Direct Aligner

Please provide your Indications for Use below.

?

Primeprint Aligner is a light curing resin intended for the treatment of tooth malocclusion in patients with developed permanent dentition. Primeprint Aligner repositions teeth by way of continuous gentle force. Intended place of use: Orthodontic/dental practices/clinics, dental laboratories

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)  
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

**K250739****Section 18-3: 510(k) SUMMARY**

- **Submitter:** Dreve Dentamid GmbH  
Max-Planck-Str. 31  
59423 Unna / Germany  
Establishment Reg. No. 1000486347
  - **Contact:** Ms. Anke Hüttenbrauck  
(Head of Regulatory Affairs)  
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  - **Official Correspondent:** Mr. Michael Breer  
(Plant Manager and Quality Management Representative)
  - **Date Prepared** November 6<sup>th</sup>, 2025
- Trade Name: Primeprint Direct Aligner  
Common Name: Aligner, Sequential  
Regulation Name: Orthodontic plastic bracket  
Regulation Number: 21 CFR 872.5470  
Regulation Class: Class II  
Review Panel: Dental  
Product Code: NXC

**Table 1:** Predicate Device (Primary)

<b>510(k)</b>	<b>Predicate Device Name</b>	<b>Company Name</b>
K212680	LuxCreo Clear Aligner System	LuxCreo Inc.

**Table 2:** Reference Device (for technological comparison only)

<b>510(k)</b>	<b>Reference Device Name</b>	<b>Company Name</b>
K232448	FREEPRINT® Splintmaster	DETAX GmbH

## DESCRIPTION

Primeprint Direct Aligner is a light-curing material for the production of aligners using the Primeprint Solution (Primeprint 385nm DLP 3D printer and Primeprint Post Processing Unit). The material is intended for the treatment of tooth malocclusion in patients with developed permanent dentition. Primeprint Direct Aligner repositions teeth by way of continuous gentle force.

The material will be used by professional users such as orthodontic and dental practices/clinics and dental laboratories.

## STATEMENT OF INTENDED USE

Light-curing material for the production of dental splints by means of 3D printing processes.

## STATEMENT OF INDICATION FOR USE

Primeprint Aligner is a light curing resin intended for the treatment of tooth malocclusion in patients with developed permanent dentition. Primeprint Aligner repositions teeth by way of continuous gentle force.

Intended place of use: Orthodontic/dental practices/clinics, dental laboratories

## MATERIAL COMPOSITION

Primeprint Direct Aligner is a mixture of (meth)acrylate-containing oligomers, monomers, photoinitiators, dyes and additives.

## COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Primeprint Direct Aligner and the predicate device have the same technological characteristics:

- Both materials are UV-light curing resins for 3D printing.
- According to ISO 20795-2 they are classified the same type of material.
- Supplied in liquid form, non-sterile and for professional use only.
- Software is used for ordering workflow.
- Both final devices are removable
- Same usage (multiple times by a single patient)
- Same duration of use.
- Same design.
- Same biocompatibility testing.

The following differences exist between the subject and the predicate device:

In the chemical composition/characterization and the manufacturing process differences exist. Primeprint Direct Aligner is made of urethanacrylate resin consisting of methacrylate whereas the Predicate is a polyurethane resin which is not the same, but it is equivalent.

Both materials are using a 3D printer with UV cured 3D printing resins and the method of manufacturing is the same. There are slight differences in the printers and curing systems being used but the reference device uses the same 3D printing and curing solution. Furthermore, the performance tests show that Primeprint Direct Aligner meets its safety and effectiveness criteria same as the predicate device.

## NON-CLINICAL PERFORMANCE TESTING

Primeprint Direct Aligner has been tested and meets the requirements of the following FDA Recognized Consensus Standard:

- ISO 20795-2:2013 - Dentistry – Base polymers – Part 2: Orthodontic base polymers

Performance testing was performed on the subject device according to ISO 20795-2 standard for curing, color, porosity, ultimate flexural strength, total fracture work, maximum stress intensity factor, flexural modulus, sorption and solubility endpoints identified in ISO 20795-2.

The subject and the predicate device were tested to ISO 20795-2 standard meeting most of the requirements. The results for ultimate flexural strength and flexural modulus demonstrated similar performance of the properties.

For the evaluation of the biological safety of the subject device ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process and ISO 7405:2018 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry were considered. Biocompatibility testing was performed according to the standards cited in the following paragraph.

The non-clinical performance testing meets the acceptance criteria and demonstrates that Primeprint Direct Aligner meets the requirements for its intended use.

## BIOCOMPATIBILITY

Primeprint Direct Aligner meets the biocompatibility requirements of the following standards:

- ISO 10993-1:2018 - Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

- ISO 10993-3: 2014 - Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-5:2009 - Biological evaluation of medical devices – Part 5: Tests for invitro cytotoxicity
- ISO 10993-10:2021 - Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017 - Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- ISO 10993-23:2021 - Biological evaluation of medical devices - Part 23: Tests for irritation
- ISO 7405:2018 - Dentistry: Evaluation of biocompatibility of medical devices used in dentistry

All tests were passed confirming biological safety of the material.

**CLINICAL PERFORMANCE DATA**

Not applicable. No human clinical testing has been performed.

**SUBSTANTIAL EQUIVALENCE**

Primeprint Direct Aligner and the Predicate LuxCreo Clear Aligner System have the same indications for use and have very similar technological properties. They are both intended for the treatment of tooth malocclusion in patients with developed permanent dentition. The final devices are designed to reposition teeth by way of continuous gentle force.

**Table 3:** Comparison with Predicate Device

<b>Attributes</b>	<b>Subject device Primeprint Direct Aligner</b>	<b>Predicate device LuxCreo Clear Aligner System</b>	<b>Substantial Equivalence Comparison Assessment</b>
510(k) Number	K250739	K212680	N/A
Product Code	NXC	NXC	Same
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	Same
Regulation Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Same
Device Classification	Class II	Class II	Same

Intended Use/ Indication(s) for Use	Primeprint Aligner is a light curing resin intended for the treatment of tooth malocclusion in patients with developed permanent dentition. Primeprint Aligner repositions teeth by way of continuous gentle force.	LuxCreo Clear Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The LuxCreo Clear Aligner System repositions teeth by way of continuous gentle force.	Same
Method of Manufacturing	UV Light-cured 3D printing	UV Light-cured 3D printing	Same
Resin	Light-curing resin	Light-curing resin	Same
Chemical Characterization	Urethanacrylate resin consisting of methacrylate	Polyurethane resin	Equivalent
Material type	Type 2 light-activated material	Type 2 light-activated material	Same
Form	Liquid resin, non-sterile	Liquid resin, non-sterile	Same
OTC/Rx	Rx	Rx	Same
Final device	Removable aligner for single patient, multiple use, 20-22 hours/day	Removable aligner for single patient, multiple use, 20-22 hours/day	Same
Performance testing	ISO 20795-2:2013	ISO 20795-2:2013	Similar
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23 ISO 10993-11	ISO 10993-5 ISO 10993-10  ISO 10993-11	Same

The difference in the chemical composition have not raised extra safety and performance concerns. The biocompatibility tests and the performance tests show that Primeprint Direct Aligner meets its safety and effectiveness criteria as the cited predicate device (for details please refer to Section Predicates and Substantial Equivalence of this submission).

Testing and data demonstrate substantial equivalence of Primeprint Direct Aligner to the Predicate.

Primeprint Direct Aligner and predicate devices K212680 are:

1. Same intended use/ indication(s) for use
2. Same intended population
3. Same physical property
4. Same material type
5. Same mode of action
6. Same method of use
7. Same duration of use
8. Required using software for ordering workflow in the same way

- 9. Removable devices
- 10. Similiar DLP/ SLA 3D printer UV cured 3D printing resin for medical device manufacturing
- 11. Having software involved during the manufacturing process
- 12. Similar materials
- 13. Same biocompatibility evaluation and testing.

The reference device (K232448) is used only to support technological comparison and not for establishing substantial equivalence. The technical characteristics of Primeprint Direct Aligner are substantially equivalent to the reference device:

**Table 4:** Comparison with Reference Device

<b>Items</b>	<b>Subject device Primeprint Direct Aligner</b>	<b>Reference device FREEPRINT® splintmaster K232448</b>	<b>Substantial Equivalence Comparison Assessment</b>
Proprietary Name	---	Primeprint Splint ST	N/A
Manufacturer	Dreve Dentamid GmbH	DETAX GmbH	N/A
Intended Use/ Indication(s) for Use	Primeprint Direct Aligner is a light curing resin intended for the treatment of tooth malocclusion in patients with developed permanent dentition. Primeprint Direct Aligner repositions teeth by way of continuous gentle force.	A light-cured methacrylate-based resin used in conjunction with 3D printers (additive manufacturing) and curing systems to produce mouthguards, nightguards, splints, and repositioners.	Similar
Method of Manufacturing	UV Light-cured 3D printing	UV Light-cured 3D printing	Same
Chemical Characterization	Urethanacrylate resin consisting of methacrylate	Methacrylate-based resin	Same
Material comparison	Resin based	Resin based	Same
3D Printer/Post Curing Unit	Dentsply Sirona Primeprint Solution	Dentsply Sirona Primeprint Solution	Same

Information contained within this submission demonstrates that the Primeprint Direct Aligner:

- Has legally marketed predicate device and reference device.
- Has identical indications for use as the predicate device.
- Has similar indications for use as the reference device.
- Incorporates assumable not totally the same technological characteristics (chemical composition difference) as the predicate device.
- Incorporates the same technological characteristics (chemical composition difference) as the reference device.
- Does not raise different questions with regard to safety and effectiveness.
- Uses accepted test methods, international standards, and guidance documents to evaluate device safety and effectiveness.
- Demonstrates equivalent safety and performance characteristics as compared to the predicate devices.

## CONCLUSION

It can therefore be concluded that the Primeprint Direct Aligner manufactured by Dreve Dentamid GmbH, is substantially equivalent to the predicate device LuxCreo Clear Aligner System cleared under K212680 and the reference device FREEPRINT® Splintmaster cleared under K232448. Primeprint Direct Aligner manufactured by Dreve Dentamid GmbH is as safe, effective and substantially equivalent to the predicate device LuxCreo Clear Aligner System (K212680).