August 27, 2025

Aidite (Qinhuangdao) Technology Co., Ltd.
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lu Jiazui Rd., Pudong
Shanghai, 200120
CHINA

Re: K251415
Trade/Device Name: Additively Manufactured Aligner Resin
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC, MQC
Dated: July 29, 2025
Received: July 30, 2025

Dear Boyle Wang:

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,

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

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)*
K251415

Device Name
Additively Manufactured Aligner Resin

Indications for Use *(Describe)*
This product is suitable for making invisible orthodontic appliances by additive manufacturing (light curing 3D printing) process. The orthodontic appliance is designed for orthodontic treatment. It uses continuous gentle force to adjust tooth position, correct malocclusion, and maintain the results of completed orthodontic treatment.
It can also be used for printing splints and night guards.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K251415

This summary is submitted in accordance with 21 CFR 807.92.

1.0 Submission Sponsor

Name: Aidite (Qinhuangdao) Technology Co., Ltd.
Address 1: No.9 Dushan Road, Economic and Technological Development Zone, Qinhuangdao City, 066004 Hebei P.R.China
Address 2: No. 56 Tianchi Road,Economic and Technological Development Zone,Qinhuangdao City,066004 Hebei P.R. China
Contact: Mr. Ye Zhanfu
Tel: +86 335 8587898
Fax: +86 335 8587198

Designated Submission Correspondent

Contact: Mr. Boyle Wang
Address: Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lu Jiazui Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: info@truthful.com.cn

Date of Preparation: Jul.29th, 2025

2.0 Device Information

Trade name: Additively Manufactured Aligner Resin
Common name: Additive Manufacturing (Light Curing) Orthodontie Resin
Model: DPAS-C
Classification name: Material, Tooth Shade, Resin
Production code: NXC,MQC
Regulation number: 21 CFR 872.5470
Classification: Class II
Panel: Dental

3.0 Identification of Predicate Device and Reference Device

Predicate Device 1:

510(k) Number: K212680
Trade/Product Name: LuxCreo Clear Aligner System
Manufacturer: LUXCREO INC.

Predicate Device 2:

510(k) Number: K221022
Trade/Product Name: NextDent Ortho Flex
Manufacturer: Vertex-Dental BV

4.0 Device Description

Additively Manufactured Aligner Resin is custom plastic aligner system which are a series of doctor prescribed clear removable aligners that are used as alternative treatment for the alignment of maloccluded or misaligned teeth. This series of aligners gently move the patient's teeth in small increments from their original state to a treated state.
Additively Manufactured Aligner Resin is a light-curing resin used to print orthodontic appliances. The resin is a light yellow transparent liquid. The appliance printed by a 3D printer is de-supported, cleaned and post-cured to obtain an orthodontic appliance that can correct the patient's malocclusion. This product is a light-curing 3D printing resin composed of acrylate resin oligomers and acrylate monomers as well as initiators and additives.
Additive manufacturing (light cured) orthodontic resin is a light cured acrylic resin commonly used in the manufacture of orthodontic appliances. The resin is stored in a black HDPE bottle according to the weight of the resin liquid. The color of the resin is colorless or yellowish liquid, polymerized by UV light at 385 nm or 405 nm.

5.0 Indication for Use Statement

This product is suitable for making invisible orthodontic appliance by additive manufacturing process (light curing 3D printing process). The orthodontic appliance is designed for orthodontic treatment. It uses continuous gentle force to adjust tooth position, correct malocclusion, and maintain the results of completed orthodontic treatment.
It can also be used for printing splint and night guard.

6.0 Non-clinical Test Conclusion

Bench Testing:
- The most applicable standard for mechanical characteristics determination of the subject device is FDA-recognized version ISO 20795-2:2013 Dentistry – Base polymers – Part 2: Orthodontic base polymers.

Performance testing including Homogeneity, Surface Properties, Forming

Performance, Color, No Porosity, Flexural Strength, Flexural Modulus, Ultimate Flexural Strength, Water Solubility and Water Sorption.

All test results of above items were similar to that of the predicate device that meet the requirements of ISO 20795-2:2013. The performance characteristics of the subject device are comparable to those of the predicate device for this particular indication and raise no new or different questions of safety and effectiveness. Therefore, the subject device and the predicate device are substantially equivalent in physical properties.

• Printers Validation: Different printers are validated for processing (3D printing) using the candidate device. Additional printers post-510(k) clearance will be added to the labelling by means of the Quality Systems and within the validation plan presented in this 510(k).

Biocompatibility Testing:
The nature of body contact of materials used in the design of the Additively Manufactured Aligner Resin were classified as being Surface Devices in contact with mucosal membrane with a permanent contact duration of >30 days, repeated use. The biocompatibility testing was performed according to FDA currently-recognized versions of biocompatibility consensus standards 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.
The following biological safety aspects have been addressed:
• Cytotoxicity – ISO 10993-5
• Sensitization – ISO 10993-10
• Irritation – ISO 10993-23
• Acute Systemic Toxicity- ISO 10993-11
• Subchronic Systemic Toxicity – ISO 10993-11
• Genotoxicity – ISO 10993-3

Sterility and Shelf-Life Testing:
The device is provided non-sterile.
Based on shelf-life testing, the Additively Manufactured Aligner Resin has an unopened shelf life of 2 years. Once opened, the resin should be used within 60 days and must be protected from light exposure.

7.0 Technological Characteristics and Substantial Equivalence

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 1- Comparison of Technology Characteristics

Item	Subject Device		Predicate Device 1	Predicate Device 2		Remark
510(k) No.	K251415		K212680	K221022		--
Product Name	Additively Manufactured Aligner Resin		LuxCreo Clear Aligner System	NextDent Ortho Flex		--
Product Code	NXC	MQC	NXC	MQC	KMY	Same
Regulation No.	21 CFR 872.5470	NA	21 CFR 872.5470	NA	21 CFR 872.5525	Same
Class	Class II		Class II	Unclassified (pre amendment)	Class 1	Same
Intended Use/ Indication for Use	This product is suitable for making invisible orthodontic appliance by additive manufacturing process (light curing 3D printing process). The orthodontic appliance is designed for orthodontic treatment. It uses continuous gentle force to adjust tooth position, correct malocclusion, and maintain the results of completed orthodontic treatment. It can also be used for printing splint and night guard.		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.	NextDent Ortho Flex is a 3D print resin intended for the manufacturing of 3D printed dental splints and retainers. To retain the regulated dentition. NextDent Ortho Flex is intended exclusively for professional dental work.		Same* (Analysis 1)
Mode of Action	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays		Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays	Not publiclt available		Same with Predicate Device 1
Method of Use	Each preformed plastic tray is worn by the patient as prescribed by the dental practitioner, usually for 7-10 days, usually no more than 15 days prior to using the next sequential aligner tray		Each preformed plastic tray is worn by the patient as prescribed by the dental practitioner, usually a few weeks prior to using the next sequential aligner tray	Not publiclt available		Same with Predicate Device 1
Prescription	Rx		Rx	Rx		Same

Use				
Duration of Use	Each set of aligners can be worn for approximately 2 weeks of 20-22 hours of wear per day or according to doctor's prescription.	20-22 hours/day	Not publiclt available	Same with Predicate Device 1
Method of Manufacturing	Light-cured 3D printing	Light-cured 3D printing	Light-cured 3D printing	Same
Software Used for Ordering Workflow	Yes	Yes	Yes	Same
Application	Removable	Removable	Removable	Same
Materials	Light-cured polyurethane resin	Light-cured polyurethane resin	acrylate-based UV light cure resin	Similar
Shelf-Life	24 months	Six-month	18 months	Different (Analysis 2)
Performance Testing	Per ISO 20795-2:2013	ISO 20795-2:2013	ISO 20795-2:2013	Same
Flexural Modulus	Average 877.49 MPa	804 ± 64 MPa	Not publiclt available	Different (Analysis 3)
Ultimate Flexural Strength	Average 39.72 MPa	23.6 ± 1.9 MPa	Not publiclt available	
Water Solubility	Average 3.05μg/mm³	3.668±1.0748 μg/mm³	Not publiclt available	
Water Sorption	Average 29.94μg/mm³	19.952±6.6719 μg/mm³	Not publiclt available	
Sterile	Non-sterile	Non-sterile	Non-sterile	Same
Biocompatibility	ISO 10993-5 In vitro Cytotoxicity ISO 10993-10 Oral Mucosa Irritation ISO 10993-23 Skin Irritation ISO 10993-11 Acute Systemic Toxicity ISO 10993-11 Subacute Systemic Toxicity ISO 10993-3 Genotoxicity	ISO 10993-5 In vitro Cytotoxicity ISO 10993-10 Oral Mucosa Irritation Pyrogen ISO 10993-10 Skin Irritation in Rabbits ISO 10993-10 Skin Sensitization in Guinea Pigs (Maximization Test) ISO 10993-11 Acute Systemic Toxicity	• Cytotoxicity • Sensitization •Irritation or intra cutaneous reactivity • Subacute/sub chronic systemic toxicity • Genotoxicity • Chemical characterization	Same

Analysis*:

1) The Indication for Use of the subject device, Additively Manufactured Aligner Resin, is consistent with the combined indications of the identified predicate devices. The subject device incorporates the orthodontic therapeutic purpose of Predicate Device 1 and the dental splint manufacturing capability of Predicate Device 2. There are no new indications introduced, and the overall intended use remains consistent with legally marketed predicate devices, supporting substantial equivalence.

2) The difference in shelf life does not impact their substantial equivalence. The shelf-life validation report of the subject device demonstrates the stability of the products' performance over time, ensuring their reliability and safety during their respective shelf lives.

3) There are measurable differences among the Flexural Modulus and Ultimate Flexural Strength. The Flexural Modulus and Ultimate Flexural Strength of the subject device is better than the predicate device because the average values of the subject device were statistically significantly higher than that of the predicate device.

   Water Solubility and Water Sorption values of the subject device and the predicate devices were slight different, all tested materials conform to the requirements of ISO 20795-2:2013, the differences observed are not expected to adversely affect the safety or effectiveness of the subject device.

   Therefore, the subject device is considered substantially equivalent to the predicate devices in terms of performance characteristics.

8.0 Summary of Clinical Test

Clinical testing was not required for this submission.

9.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the subject device is substantially equivalent to the legally marketed predicated device.