December 20, 2024

Xplora 3D Europe S.L
℅ Juan Tezak
Consultant
Compliance 4 Devices
118 W Prive Cr.
Delray Beach, Florida 33445

Re: K242929
Trade/Device Name: Fas Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: November 18, 2024
Received: November 18, 2024

Dear Juan Tezak:

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242929

Device Name

Fas Aligner System

Indications for Use *(Describe)*

Fas Aligner System is intended for the orthodontic treatment of malocclusion.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K242929

510(k) Summary

Prepared December 11, 2024

I) Applicant

Submitter	XPLORA 3D EUROPE S.L
Address	C/ Juan de la Cierva 70. Arroyomolinos. 28939. Madrid – Spain
Contact	Esther Aznar
Telephone	+34 692 266297
E-mail	esther.aznar@xplora3d.com

II) Device

Trade Name	**Fas Aligner System**
Common Name	Orthodontic plastic bracket.
Classification Name	Aligner, Sequential
Regulation Number	872.5470
Product Code	NXC

III) Predicate Device

510(k) Number	K222418
Applicant	Gruppo Europeo di Ortodonzia S.r.l. (G.E.O srl)
Trade Name	Nuvola® Aligner
Classification Name	Aligner, Sequential
Regulation Number	872.5470

Reference Device

510(k) Number	K232549
Applicant	Software Nemotec S.L.
Trade Name	NemoCast
Classification Name	Orthodontic Software
Regulation Number	872.5470
Classification Code	PNN - LLZ

IV) Indication For Use

Fas Aligner System is intended for the orthodontic treatment of malocclusion.

V) Device Description

Fas Aligner System consist of a series of customized removable plastic orthodontic appliances which sequentially reposition teeth by way of continuous gentle force. This removable plastic orthodontic aligners intended as an alternative to conventional wire and bracket technology. Fas Aligner System are designed based on traditional mold impression or digital scans of the patient's dentition submitted by a dental health professional (e.g., a dentist or orthodontist).

Fas Aligner System 's staff in the Prescription and Planning area create the virtual planning including the attachments, as well as the movements they consider necessary to achieve the intended tooth correction. For this process the staff uses the following previously released software Nemocast (K232549).
The 3D specialists use the planned data to produce the complete product design. The responsible of the Planning/Prescription department reviews the design to verify that it has been done as required and, if necessary, proposes changes.

Once the design has been approved by the clinician, the next phase of printing and preparation of models is carried out. This phase takes place in the Printer Room and is carried out by 3D Printing Technicians. For the entire manufacturing process, the models are identified with the clinical case number.
The thermoforming equipment is used for the manufacturing process of the aligners. The printed model is placed on the platform and the thermoforming sheet is placed, which is made with material previously released by means of the K200125 (Erkodur).
Once the printed thermoforming sheet is obtained, the contour of the thermoforming sheet is cut out, eliminating the edges. The gingival margins are trimmed.
The product is not sent sterile, it is cleaned to remove all residues that may have remained from the manufacturing process.
The product, the splint, is placed in labeled bags. The aligners are sent back to the dentist for distribution to the patient in sequential stages and that the dentist checks the aligners for fit and function and monitors the treatment from the first aligner until treatment is completed.

VI) Comparison of Technological Characteristics

	Subject Device	**Predicate Device**	**Comparation**
Device Name	Fas Aligners System	Nuvola® Aligner	
510k Number	Pending	K222418	
Manufacturer	Xplora 3D Europe S.L.	Gruppo Europeo di Ortodonzia S.r.l. (G.E.O srl)	
Classification Regulation #	21 CFR 872.5470	21 CFR 872.5470	Same
Name Product	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Same
Code	NXC	NXC	Same
Class	II	II	Same
Indications for use	Fas Aligner System is intended for the orthodontic treatment of malocclusion.	Nuvola® aligner is intended for the orthodontic treatment of malocclusion.	Same
Mode of action	Sequential aligners apply continuous gentle force to the teeth and/or position mandible forward.	Sequential aligners apply continuous gentle force to the teeth and/or position mandible forward.	Same

Device Description	Sequential thermoformed plastic aligners	Sequential thermoformed plastic aligners	Same
Description of use	Aligners are worn for approximately 1-2 weeks of 20- 22 hours of wear per day, after which it is replaced by the next stage aligners. This is repeated for duration as prescribed by the Dental Practitioner.	Aligners are worn for approximately 1-2 weeks of 20- 22 hours of wear per day, after which it is replaced by the next stage aligners. This is repeated for duration as prescribed by the Dental Practitioner.	Same
Patient Population	Children, Adolescents and Adults	Children, Adolescents and Adults	Same
Material	Thermoplastic polymer PET-G	Thermoplastic polymer PET-G	Same
Material Properties	Acceptable materials properties established for use as aligner (polyethylene terephthalate glycol PET-G) Erkodur (K200125)	Acceptable materials properties established for use as aligner (polyethylene terephthalate glycol PET-G) Erkodur (K200125)	Same
Manufacturing Process	Thermoforming on models	Thermoforming on models	Same
Manufacturing Process Validation	An internal manufacturing Process Validation was performed	An internal manufacturing Process Validation was performed	Same
3D software for tooth alignment	Nemocast (K232549)	3Shape Ortho System (K152086)	Different

As for the dental software for tooth alignment, which is the only difference, Xplora 3D uses the FDA-cleared Nemocast software (K232549), while G.E.O. uses its own software: 3Shape Ortho System (K152086). Both use digital scans to generate images of the final treated states and the intermediate steps to reach the final state, and convert those files to produce the series of customized aligners.

VII) Summary of Non-Clinical Testing

The use of thermoplastic materials for sequential aligners intended to treat malocclusions has been well documented in scientific literature regarding incremental tooth moving forces. However, durability test was conducted on the aligners. Real world use was simulated to ensure that the aligner material and manufacturing process produced aligners that were suitable for their prescribed period of use.

An internal manufacturing validation was performed to test the manufacturing process for Fas Aligner System. The robustness of the process was demonstrated from 3D printing through thermoforming.

The thermoplastic material used for Fas Aligner System has passed the required testing for material characterization (see K200125). Biocompatibility testing for the aligner material, the only patient contacting material, was conducted in accordance with International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation ans testing within

a risk management process". Only cytotoxicity testing according to ISO 10993-5:2009 was performed on final manufactured Aligner.

VIII) Summary of Clinical Testing

No clinical testing was performed in support of this submission.

IX) Conclusion

The Fas Aligner System device has the same intended use and indications for use as the previously cleared Nuvola® Aligner (K222418). In addition, the Fas Aligner System has the same technological characteristics, and principles of operation as its predicate.

The software differences between the Fas Aligner System and its predicate device do not raise new questions of safety or efficacy.

Thus, the Fas Aligner System device is substantially equivalent previously cleared similar devices.