January 15, 2022

Precision Align LLC.
℅ Na Zhang
Project Manager
evo820, LLC
1 Bay Street
Rancho Mission Viejo, California 92694

Re: K212772
Trade/Device Name: Precision Align
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: December 06, 2021
Received: December 09, 2021

Dear Na Zhang:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For Michael E. Adjodha, M.ChE.
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)*
K212772

Device Name
Precision Align

Indications for Use *(Describe)*
The Precision Align aligners are indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The Precision Align aligners positions teeth by way of continuous gentle force.

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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Section V. 510(k) Summary

SUBMITTER

Date Prepared: 12/10/2021

Submitter: Precision Align LLC.

1825 NE 45th Street Suite A
Fort Lauderdale, Florida 33308
United States of America

Official Contact: Chris Freeman
MRGM
Tel:954-837-8367
Email: drchris@precisionalignco.com

DEVICE

Trade/Proprietary Name:	Precision Align
Common Name:	Aligners, Sequential
Classification Name :	Orthodontic Plastic Bracket
Classification Regulations:	21CFR 872.5470
Product Code:	NXC
Device Classification:	Class II
Classification Panel:	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PRIDICATE DEVICE

Predicate Device:	K211010	Illusion Aligners	Laximi Dental Exports Pvt Ltd.
Reference Device:	K191838	ClearForm Aligners	Motor City Lab Works
Reference Device for Software	K200772	ULab Systems uDesign Software	ULab Systems, Inc.

DEVICE DESCRIPTION

The Precision Align Aligner is a series of clear, light weight thermoformed plastic aligners designed to be worn in sequence to facilitate the movement to the teeth to the final desired position. The sequential aligners introduce incremental movements that move teeth by way of gentle continuous force. The aligners are to be worn 20 to 22 hours a day and are to be removed for eating and for cleaning. Generally the typical wear time for each aligner is a two weeks duration prior to being replaced by the next aligner in sequence.

A digital or traditional mold impression of the patient's dentition is provided by a dental health professional (e.g. orthodontist or dentist). From the digital data of the patient's dentition, a specialized orthodontic CAD/CAM software is used to develop treatment plan. Using the software, dental technicians design a series of intermediate models corresponding to each stage of treatment, gradually realigning the patient's teeth according to the dental health profession's prescription.

The prescribing doctor reviews and approves the model scheme and treatment plan before the molds/models are produced.

Once approved, the specialized orthodontic software is used to generate standard format 3D files which are used to physically produce each model/mold in the treatment plan for aligner fabrication. Precision Align Co. produces the aligner trays by thermal forming a plastic sheet over each model in the treatment plan. The trays are provided to the dental health care professional who provides them to the patients in sequential stages, confirming fit and design. The dental health professional monitors treatment from the moment of the first aligner is delivered to when the final aligner is finished and treatment is complete. The aligners are held in place by pressure and can be removed by the patient at any time.

INDICATIONS FOR USE

The Precision Align Aligners are indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The Precision Align Aligners position teeth by way of continuous gentle force.

COMPARISON OF TECHNOLOGICAL WITH THE PREDICATE DEVICE

The subject device is substantial equivalent in intended use and technological characteristics to predicate devices shown above. Below is a summary table comparing the subjective device with the primary predicate and an additional reference predicate device.

Features	Submission Device	Predicate Device	Reference Predicate Device
Manufacture	Precision Align LLC.	Laximi Dental Exports Pvt Ltd.	Motor City Dental Lab
Trade Name	Precision Align	Illusion Aligners	ClearfForm Aligners
510(k) Number	K212772	K211010	K191838
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	21 CFR 872.5470
Classifications	Class II	Class II	Class II
Product Code	NXC	NXC	NXC

Indications for Use	The Precision Align Aligners are indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). The Precision Align Aligners position teeth by way of continuous gentle force.	The Illusion Aligners indicated for use in the alignment of permanent teeth(i.e. all second molars) through orthodontic treatment of misalignment and malocclusion.	ClearForm Aligners are indicated for the alignment of teeth in patients with permanent dentition (i.e. all second molars) during orthodontic treatment of malocclusions. The aligners position teeth by way of continuous gentle forces
Mode of Actions	Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastics trays	Orthodontic movement occurs through continuous gentle forces applied to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.
Material	PETG, thermoplastic	PETG (Polyethylene terephthalate glycol) material	Essix thermoplastic
Biocompatible	Yes	Yes	Yes
Software	The standard ortho dental software uses a scan of tooth impression or a digital scan to generate the image of a final, treated state and then interprets a series of images that represent intermediate teeth states. Once the dental practitioner approves the treatment plan, the software converts the files to produce the series of patient specific aligners.	The scanned data (digital CAD/CAM models or patient models) are imported into specialized dental software for treatment planning. Laximi Dental Exports Pvt Ltd, Inc. utilizes a software application to plant the treatment by creating a series of sequential models that gradually position the teeth into their final desired position. The treatment plan is sent to the doctor for approval. Upon approval , a 3D printer is used to create	Standard dental software for tooth alignment uses digital scan (untreated state) to generate the image of a final, provisional treated state and then interprets a series of images that represent intermediate teeth states. The dental practitioner then reviews these images and has the option to reject or request modifications to the set-up prior to approving it for aligner fabrication. Once the dental practitioner approves the treatment plan, the software

		the molds needed for each treatment step to provide the surface around which the aligner is thermoformed	converts the files to produce the series of 3D models used to produce thermoformed aligners
Manufacture Method	Thermoforming	Thermoforming	Thermoforming
Rx or OTC	Rx	Rx	Rx
Sterility	Non-sterile	Non-sterile	Non-sterile
Design			

Differences compare Precision Aligners to Predicate Device

Precision Aligners	**S& E Effect**	**Illusion Aligners**
Precision Align LLC. uses ULab Systems K200772	No Effect. ULab systems K20072 is FDA 510(k) cleared software, the use /manufacturing process has been validated by Precision Align LLC.	Laxmi Dental Exports Pvt. Ltd, Inc. uses 3Shape Software K180941 and K152086
Precision Align LLC. provided biocompatibility testing results (cytotoxicity, Skin irritation and Sensitization) of the thermoplastic PETG material according to ISO10993. Precision Align LLC. also performed biocompatibility testing(cytotoxicity) of the finished device(Precision Aligner) according to ISO10993	No Effect. Additional cytotoxicity testing of the finished device provide more insurance of the safety and effectiveness of using the subject device.	Laxmi Dental Exports Pvt. Ltd, Inc. performed biocompatibility testing(cytotoxicity, Skin irritation and Sensitization) of the thermoplastic PETG material according to ISO10993

The intended use of the Precision Align aligner is the same as the primary predicate device. They are both intended for correcting dental malocclusion patients with permanent dentition. It has similar technological characteristics and fabricated by a similar manufacturing process to the predicate device. There are minor difference comparing Precision Aligner with the predicate device Illusion Aligner which do not affect substantial equivalence or safety and effectiveness. Therefore, the Precision Align Aligner is considered to be substantially equivalent to the predicate device based on a comparison of intended use and technological characteristics.

Non-Clinical PERFORMANCE DATA

Non-clinical testing have been conducted to verify that the Precision Align Aligner meets all design specification which supports the conclusion that it's substantially equivalent (SE) to the predicate device.

Software used for treatment planning and creation of models/mold for Precision Align Aligner is manufactured by ULab Systems, Inc. It is a 510(k) clearance (K200772) software under product code PNN for intended use.

An internal manufacturing validation was performed to demonstrate the dimensional accuracy of the manufacturing for Precision Aligner. The critical aspects of the manufacturing process were assessed for accuracy. The final aligner fitness was evaluated according to the in-house fitness acceptance criteria.

Translational measurement were within 0.150mm (150microns) of the target input value, the predefined tolerance of the manufacturing process. There were no statistical difference in the difference in the values measured from any of the groups. The testing results are within the acceptance criteria to demonstrate dimensional accuracy. Additionally, the final aligner fitness evaluation by a trained physician demonstrate all the aligners including in the study passed and were deemed an excellent fit .

The biocompatibility evaluation determined that Precision Align Aligner and the predicate devices are composed of the same material, fabricated by the similar manufacturing processes, and has identical method of use, which can conclude that Precision Align Aligners are biocompatible for their intended use.

Biocompatibility testing for the aligner material, the only patient contacting material, was conducted by the material manufacture in accordance with International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".

- Test for *in vitro* cytotoxicity : Elution Method ISO10993-5
- Skin Irritation Test in New Zealand White Rabbits ISO10993-10
- Sensitization Test in Guinea Pigs(Guinea Pig maximization Test) ISO10993-10

Additional cytotoxicity testing according to ISO 10993-5:2009 was performed on the final manufactured Precision Align Aligners .

- Test for *in vitro* cytotoxicity : Minimal Essential Media (MEM) Elution ISO10993-5

Non-Clinical physical properties of the device material have been tested by the material manufacture complying with the following standard

- Tensile Strength at Break(MPa) ASTM D638
- Tensile Stress at Yield (MPa) ASTM D638

- Elongation at Break (%) ASTM D638
- Elongation at Yield (%) ASTM D638
- Tensile Modulus (MPa) ASTMD638
- Water Absorption at 23°C, 24h ASTM D570

CLINICAL PERFORMANCE DATA

The clinical performance of sequential aligners (product code NXC) has been well established since the first device of this category was cleared by the FDA in 1998. The Precision align aligners have equivalent indication and method of use to its primary and reference predicate devices, therefore there was no clinical testing necessary to support this device.

CONCLUSIONS

The subject device has very similar technological characteristics (i.e. design, function, principle of operation, materials, biocompatibility and sterilization) to the predicate device . The intended use and indications for use of the subject device are the same as the predicate device.

In conclusions, the device is substantially equivalent based on a comparison of intended use, and technological characteristics and the device is considered to be safe and effective for its intended use.