August 8, 2024

Laxmi Dental Export PVT. LTD
℅ Jennifer Day
Regulatory Consultant
Prime Path Medtech
811 Lakeview Dr.
Shoreview, Minnesota 55126

Re: K233356
Trade/Device Name: Illusion Aligner Pro: Illusion Aligner FLX
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: September 29, 2023
Received: September 29, 2023

Dear Jennifer Day:

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.

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)*
K233356

Device Name
Illusion Aligner Pro
Illusion Aligner Flx

Indications for Use *(Describe)*
Illusion Aligners Pro are indicated for use in the alignment of permanent teeth (i.e. all second molars) through orthodontic treatment of misalignment and malocclusion.

Illusion Aligner Flx are indicated for use in the alignment of permanent teeth (i.e. all second molars) through orthodontic treatment of misalignment and 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.

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510(k) Summary

This Traditional 510(k) Summary information is being submitted in accordance with Title 21, CFR Section 807.92.

1. SUBMITTER

Name of Manufacturer/Owner of 510(k):	Laxmi Dental Exports Pvt Ltd Survey No. 201/1, Village Gundale, Boisar Chillar Highway, Boisar, District – Palghar, India – 401501
FDA Establishment Registration Number:	3004793856
Primary Contact Person:	Samee Merchant
Email Address	sameer@laxmidental.com
Phone Number	022 - 61437900
Fax Number	022 - 61437999
Date of Summary Prepared	7/9/2024

2. PURPOSE OF THIS SUBMISSION

This submission seeks clearance for the Illusion Aligner Pro and Illusion Aligner Flx; they are substantially equivalent to DailyMate Orthodontic Aligner System (K212803) and Smylio Invisible Clear Aligners (K212660), respectively.

3. SUBJECT DEVICES

Device Name: Illusion Aligner Pro

Common Name or Usual Name: Aligner, Sequential

Classification Name: Orthodontic plastic bracket (21 CFR 872.5470)

Regulatory Class: II (21 CFR 872.5470)

Product Code: NXC (21 CFR 872.5470)

Device Name: Illusion Aligner Flx

Common Name or Usual Name: Aligner, Sequential

Classification Name: Orthodontic plastic bracket (21 CFR 872.5470)

Regulatory Class: II (21 CFR 872.5470)

Product Code: NXC (21 CFR 872.5470)

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4. PREDICATE DEVICES

Illusion Aligner Pro – Predicate Devices

Predicate Device 510(K) Number: K212803

Predicate Device Name: DailyMate Orthodontic Aligner System

Common Name or Usual Name: Aligner, Sequential

Classification Name: Orthodontic plastic bracket (21 CFR 872.5470)

Regulatory Class: II (21 CFR 872.5470)

Product Code: NXC (21 CFR 872.5470)

Manufacturer: 3D Global Biotech Inc

Illusion Aligner Flx – Predicate Devices

Predicate Device 510(K) Number: K212660

Predicate Device Name: Smylio Invisible Clear Aligners

Common Name or Usual Name: Aligner, Sequential

Classification Name: Orthodontic plastic bracket (21 CFR 872.5470)

Regulatory Class: II (21 CFR 872.5470)

Product Code: NXC (21 CFR 872.5470)

Manufacturer: SMYLIO, INC.

5. INDICATIONS FOR USE

The Illusion Aligners Pro and Illusion Aligner Flx are indicated for use in the alignment of permanent teeth (i.e., all second molars) through orthodontic treatment of misalignment and malocclusion.

6. DEVICE DESCRIPTION

A dental health professional (e.g., an orthodontist or a dentist) prescribes the Illusion Aligners Pro and Illusion Aligner Flx are based on an assessment of the patient's teeth. The dental health professional (dentist/orthodontist) takes either the intraoral scans or physical impressions of the patient's teeth, determines the required corrections to align the teeth, and 3Shape's Ortho System is used for treatment planning. Illusion Aligners Pro and Illusion Aligner Flx are intraoral thermoplastic appliances that are worn 20 to 22 hours per day and are designed to be used in a sequence, each aligner providing a gentle continuous force, to allow for the movement of teeth to the final desired position. The aligners are to be removed for eating and for cleaning. Illusion Aligners Pro and Illusion Aligner Flx are fabricated using a three- step process.

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The first step is to obtain the dimensions and details of the patient's dentition. This is generally done using an intraoral scan or a physical impression. This scanned data (digital CAD/CAM models or patient models) is imported into specialized dental software for treatment planning.

The second step is the printing of 3D models of the treatment plan for use in step 3 (thermoforming). In the second step, Illusion Aligners Pro and Illusion Aligner Flx utilizes a software application to plan 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 the models needed for each treatment step to provide the surface around which the aligner is thermoformed.

The final step is the thermoforming of a plastic sheet material to each of the sequential treatment steps. This process is done using standard thermoforming equipment and the appropriate material as specified. The trays are provided to the dental health care professional who provides them to the patient in sequential stages, confirming fit and design. The dental health professional monitors treatment from the moment the first aligner is delivered to when the final aligner is finished, and treatment is complete

7. TECHNOLOGICAL CHARACTERISTICS

A comparison of the relevant technological characteristics between the subject and primary predicate devices is provided in table-1 that follows.

8. MATERIALS

The Illusion Aligners Pro is made up of polyurethane while Illusion Aligner Flx is made up of co-polyester and polyurethane composite. The thickness and weight of the test item is 0.8 mm and 10 grams respectively. The DailyMate aligners are produced from polyurethane. The Smylio Invisible Clear Aligners are produced from co-polyester and polyurethane composite.

9. COMPARISON WITH THE PREDICATE DEVICES

The Illusion Aligners Pro and the predicate device (DailyMate) consist of the same ingredients. They have the same intended use, similar designs, and performance, and meet the biocompatibility requirements.

The Illusion Aligner Flx and the predicate device (Smylio Invisible Clear Aligners) consist of the same ingredients. They have the same intended use, similar designs, and performance, and meet the biocompatibility requirements.

The table below compares the subject device to the predicate and reference devices.

Table-1. Illusion Aligners Pro predicate comparison table.

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Comparison Parameters	Subject Device (Illusion Aligners Pro)	Predicate Device (DailyMate aligners)
510K Number	K233356	K212803
Indication for Use	The Illusion Aligners Pro is indicated for use in the alignment of permanent teeth (i.e., all second molars) through orthodontic treatment of misalignment and malocclusion	The DailyMate Orthodontic Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition. The aligner system repositions teeth by way of continuous gentle force.
Product Code	NXC	NXC
Intended Population	Individuals with permanent dentition	Individuals with permanent dentition
OTC or Rx	Rx	Rx
Raw Material Used	Polyurethane	Polyurethane
Mode of Action	The aligner is an orthodontic appliance intended for intra-oral use. Individual devices will be used between 20 – 22 hours per day for a period ranging from one to three weeks The corrective forces to align teeth are primarily generated by the difference between the starting tooth position and the planned tooth position defined by the tray.	Based on the clinician's treatment plan, each aligner is used for a defined period of time to exert gentle force to achieve progressive realignment of the teeth. This occurs over time until the final correction has been achieved.

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Table-2. Illusion Aligners Flx predicate comparison table.

Comparison Parameters	Subject Device (Illusion Aligner Flx)	Predicate Device (Smylio Invisible Clear Aligners)
510K Number	K233356	K212660
Indication for Use	The Illusion Aligner Flx is indicated for use in the alignment of permanent teeth (i.e., all second molars) through orthodontic treatment of misalignment and malocclusion	The Smylio Invisible Clear Aligners is indicated for the alignment of teeth during orthodontic treatment of malocclusion.
Product Code	NXC	NXC
Intended Population	Individuals with permanent dentition	Individuals with permanent dentition
Mode of Action	Orthodontic tooth movement occurs through forces applied by the device to the dentition as each tooth follows the programmed displacement based on a doctor's prescription	Orthodontic tooth movement occurs through forces applied by the device to the dentition as each tooth follows the programmed displacement based on a doctor's prescription
OTC or Rx	Rx	Rx
Raw Material Used	Co-polyester and polyurethane composite	Thermoplastic polyurethane polyester composite resin
Anatomical Site of Use	Oral Cavity	Oral Cavity
Mode of Action /Operating Principle	The aligner is an orthodontic appliance intended for intra-oral use. Individual devices will be used between 20 – 22 hours per day for a period ranging from one to three weeks The corrective forces to align teeth are primarily generated by the difference between the starting tooth position and the planned tooth position defined by the tray.	Continuous gentle force applied to teeth following the prescribed and approved treatment plan to achieve orthodontic movement

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10. SUBSTANTIAL EQUIVALENCE DISCUSSION

Illusion Aligners Pro and Illusion Aligner Flx have been subjected to ISO 10993 biocompatibility studies to demonstrate the device is as safe as its predicate device. The performance tests were conducted to demonstrate that the subject device is as effective as its predicate device.

Biocompatibility Testing

Per ISO 10993-1: 2018, Illusion Aligner Pro and Illusion Aligner Flx direct tissue-contacting, surface device contacting mucosal membrane for > 30 days due to treatment consisting of multiple aligners worn for 7 days consecutively. Thus, the aligners are permanent tissue contacting devices.

The subject device was evaluated for:

In Vitro Cytotoxicity (ISO 10993-5:2009) Skin Sensitization (ISO 10993-10: 2021) Intracutaneous Reactivity (ISO 10993-23:2021)

Clinical Studies

No clinical study was conducted.

11. CONCLUSIONS

Based on the comparison analysis, performance tests, biocompatibility tests and animal study provided in this submission, the subject device, Illusion Aligners Pro and Illusion Aligner Flx are demonstrated to be as safe and effective as the legally marketed predicate device,

DailyMate aligners and Smylio Invisible Clear Aligners. So, the subject devices are considered Substantially Equivalent (SE) to the predicate devices.

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