April 26, 2021

Laxmi Dental Exports Pvt Ltd
% Rafael Aguila
Responsible Third-Party Official
Accelerated Device Approval Services
6800 S.W. 40th Street, Ste. 403
Ludlum, Florida 33155

Re: K211010
Trade/Device Name: Illusion Aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: April 3, 2021
Received: April 5, 2021

Dear Rafael Aguila:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K211010

Device Name
Illusion Aligners

Indications for Use *(Describe)*
The Illusion Aligners 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.

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510(k) Summary

Submitter Name:	Laxmi Dental Exports Pvt Ltd.
Submitter Address:	Survey No. 201/1, Village Gundale, Boisar Chillar Highway, Boisar, District – Palghar, India – 401501
Phone Number:	0091 9820268438
Contact Person:	Sameerl Merchant
Date Prepared:	November 04,2020
Device Trade Name:	Illusion Aligners
Common Name	Aligner, Sequential
Classification Name	Orthodontic Plastic Bracket
Number	21 CFR 872.5470
Product Code	NXC
Regulatory Class	2
Primary Predicate Device:	K173784, Smylio Invisible Clear Aligner
Statement of Indications for Use	The Illusion Aligners indicated for use in the alignment of permanent teeth (i.e. all second molars) through orthodontic treatment of misalignment and malocclusion.
Device Description and Summary of Technological Characteristics	Illusion Aligners are intraoral thermoformed plastic aligners that are worn at least 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 are fabricated using a ten-step process. The Step 1 is to obtain the dimensions and details of the patient's baseline dentition. This is generally done using an oral scan data or a physical impression. Step 3, the scanned data (digital CAD/CAM models or patient models) are imported into specialized dental software for treatment planning. In the Step 3, Laxmi Dental Exports Pvt Ltd, Inc. 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. Step 4, the treatment plan is sent to the doctor for approval. Upon approval, a 3D printer is used to create the molds needed for each treatment step to provide the surface around which the aligner is thermoformed. Step 5 is the printing of 3D models of the treatment plan for use in Step 7 thermoforming. The thermoforming process is accomplished using a standard thermoforming equipment and the appropriate material as outlined in this submission.

Mechanism of Action	In the same manner as the predicate device, each aligner exerts gentle force to achieve progressive realignment of the teeth until the final correction has been attained. This is based on the treatment plan and proceeds over time.
Device Testing	<u>Biocompatibility</u> Contact of the device to the patient's oral tissue requires the Aligners material to be biocompatible. The thermoplastic PETG (Polyethylene terephthalate glycol) material has been tested according to Good Laboratory Practices for its biocompatibility according to ISO 10993, as follows: Part 5 (Cytotoxicity Elution - MEM) Part 10 (Skin Irritation) Part 10 (Guinea Pig Maximization Test) <u>Animal | Human Testing</u> No human testing is required for this product because it is composed of the same materials and has a similar design and method of manufacture/fabrication in comparison to the predicate device.
Non-Clinical Physical Properties Testing:	Device material tested to the following standards and meet the acceptance criteria • Elongation @ Yield (%) ASTM D638 • Elongation @ Break (%) ASTM D638 • Tensile @ Yield (PSI) ASTM D638 • Tensile Strength (PSI) ASTM D638 • Tensile Modulus (PSI) ASTM D638 • Water Absorption (%)24 hours @ 23°C ASTM D570

Trade Name:	Submission Device Illusion Aligners	Predicate Device K173784 Smylio Invisible Clear Aligners
510(k) Number		K173785
Manufacturer	Laxmi Dental Exports Pvt Ltd	Smylio
Classification #, Product Code Device Class	21 CFR 852.5470 NXC 2	21 CFR 852.5470 NXC 2
Intended Use	The Illusion Aligners indicated for use in the alignment of permanent teeth (i.e. all second molars) through orthodontic treatment of misalignment and malocclusion.	Smylio Invisible Clear Aligners is indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.
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.
Method of Use	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 Aligners 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 Aligners tray.
Material	PETG (Polyethylene terephthalate glycol) Material	Thin thermoformed polyurethane
Biocompatible	Yes	Yes
OTC or Rx	Rx	Rx
Software Use	Yes	Yes
Sterile	No	No

Differences between Illusion Aligners compared to predicate device

Illusion Aligners	S & E Effect	Smylio K173784
Laxmi Dental Exports Pvt Ltd. prepares the treatment plan in Step 2 of the manufacturing process for subsequent approval by a doctor.	No effect, both treatment plans are doctor approved.	Smylio K173784 doctor prepares the treatment plan
Laxmi Dental Exports Pvt Ltd, Inc. uses 3Shape Software K180491 and K152086	No effect, 3Shape Software K180491 and K152086 are FDA 510K cleared, the use/manufacturing process has been validated by Laxmi	Smylio uses 3Shape Software K152086
Laxmi uses PETG (Polyethylene terephthalate glycol) thermoforming material for the aligner	No effect, PETG (Polyethylene terephthalate glycol) material is manufacturing validated and biocompatible.	Smylio Uses Zendura polyurethane

Laxmi Dental Exports Pvt Ltd, Inc. biocompatibility summary applied ISO 10993 • -5, Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity • -10, Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	No effect on biocompatibility. ISO 7405 directly references the same test as conducted using ISO 10993 et.al.	Smylio biocompatibility summary references ISO 7405, Dentistry — Evaluation of biocompatibility of medical devices used in dentistry

The intended use of the Illusion Aligners is the same to that of the primary predicate device as they are both intended for correcting dental malocclusion in patients with permanent dentition. It has a similar technological principle, and the device characteristics are similar to the predicate device. The mode of operation and the manufacturing process used to fabricate the aligner trays is the same as the predicate device. There are minor differences comparing Illusion Aligners to the predicate Smylio Invisible Clear Aligners which do not affect substantial equivalence or safety and effectiveness.

Substantial Equivalence Conclusion

Thus, based on the above it can be concluded that Illusion Aligners is substantially equivalent to the predicate device.