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U.S. FOOD & DRUG ADMINISTRATION

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 -S

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

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.

(b)(5)

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.

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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 Adjodha
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

April 26, 2021</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Bobak Shirmohammadi.

 *** This is a system-generated email notification ***

I. Cover Letter - 510(k) Third Party Review

Date: April 3rd, 2021

FDA – CDRH
Document Control Center – WO66-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: New 3rd Party Review Memo

A. Purpose of Submission: NEW DEVICE

B. Name and Address of the 3P Review Organization
Rafael Aguila, *Responsible Third-Party Official*
Accelerated Device Approval Services, LLC
6800 S.W. 40th Street, Ste. 403
Ludlum, FL 33155-3708
Tel.: 1-866-669-8370
E-Mail: support@510k-review.com

C. Name and Address of the 510(k) Submitter
Laxmi Dental Exports Pvt Ltd. - Survey No. 201/1, Village Gundale, Boisar Chillar Highway, Boisar, District – Palghar, INDIA – 401501

D. Device Name
Trade or Proprietary Name: Illusion Aligners
Common or Usual Names: Orthodontic Plastic Bracket **Class:** II
Classification Regulation Number: 21 CFR 872.5470 **Product Code:** NXC
FDA classification regulation name: Aligner, Sequential

E. Recommendation: (b)(4)

F. The date that the 510(k) submission was received by the Accredited Person was on November 13, 2020

We have enclosed the following materials:

II. Authorization Letter from the Applicant.
III. 510(k) Third Party Submission Certification.
IV. Conflict of Interest Declaration and Certification - Final Reviewer.
V. Conflict of Interest Declaration and Certification - Product Specialist.
VI. An acceptance review of the 510(k) submission based on objective criteria using the RTA checklist.
VII. 510(k) Third Party Review Memorandum.

Sincerely,

(b)(6)

Rafael Aguila, RAC
Responsible Third-Party Official

II. Authorization Letter from the Applicant

Authorization for the Third-Party Review

Accelerated Device Approval Services ("ADAS")
1030 15th Street NW
Washington, D.C. 20005
Tel. 1-866-669-8370
support@510k-review.com

Laxmi Dental Lab USA Inc.
100 Hollister Rd
Teterboro, NJ 07608

Dear FDA Director,

Laxmi Dental Lab USA Inc. hereby authorizes Accelerated Device Approval Services ("ADAS") to submit the enclosed 510(k) to the FDA on our behalf, discuss its content with the FDA, and function as the Accredited Person to perform the third-party review.

(b)(4)

Signature of Company Representative: (b)(6)

Print Name: Kunal Merchant

Date: 11/13/2020

III. 510(k) Third Party Submission Certification

1. I certify that Accelerated Device Approval Services, LLC continues to meet the personal qualifications and prevention of conflict of interest criteria reviewed by FDA;

2. In addition, I state that Accelerated Device Approval Services, LLC believes that statements made in the review are true and accurate to the best knowledge of Accelerated Device Approval Services, LLC;

3. The reported information accurately reflects the data reviewed and that no material fact has been omitted;

4. Accelerated Device Approval Services' review is based on the 510(k) that is attached with the review; and

5. Accelerated Device Approval Services, LLC understands that the submission of false information to the government is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Sincerely,

(b)(6)

Rafael Aguila
Responsible Third-Party Official / Owner
April 3rd, 2021

IV. Conflict of Interest Declaration and Certification - *Final Reviewer*

For the review of the 510(k) submission from:

510(k) Applicant's Name: Laxmi Dental Exports Pvt Ltd.

Device Name: Illusion Aligners

Initials

(b)(6)

I have read and understand Accelerated Device Approval Services' Conflict of Interest and Confidentiality Procedure, regarding conflict of interests and the attachments accompanying the procedure and am aware of my responsibilities under them.

I have not been employed within the last twelve months by the firm who submitted the 510(k) for evaluation.

I did not charge fees contingent or based upon the recommendation for initial classification (SE decision).

I have not performed testing in connection with this specific device 510(k)

I understand that the Accredited Person (AP) program requires that the Accredited Person or any of its personnel involved in 510(k) reviews, which includes those who have authority over the review process, have no ownership or other financial interest in a device manufacturer or distributor that presents the appearance of a conflict of interest.

I do not participate in the design, manufacture or distribution of any medical device.

I did not provide consultative services to the Sponsor regarding specific device 510(k) or participate in the preparation of the 510(k).

I have not performed a 510(k) review where I have a personal relationship with the Sponsor or the application correspondent.

(b)(6)

Konrad Kobel
Final Reviewer
February 23rd, 2021

V. Conflict of Interest Declaration and Certification - *Product Specialist*

For the review of the 510(k) submission from:

510(k) Applicant's Name: Laxmi Dental Exports Pvt Ltd.

Device Name: Illusion Aligners

Initials	
	I have read and understand Accelerated Device Approval Services' Conflict of Interest and Confidentiality Procedure, regarding conflict of interests and the attachments accompanying the procedure and am aware of my responsibilities under them.
	I have not been employed within the last twelve months by the firm who submitted the 510(k) for evaluation.
	I did not charge fees contingent or based upon the recommendation for initial classification (SE decision).
	I have not performed testing in connection with this specific device 510(k)
(b)(6)	I understand that the Accredited Person (AP) program requires that the Accredited Person or any of its personnel involved in 510(k) reviews, which includes those who have authority over the review process, have no ownership or other financial interest in a device manufacturer or distributor that presents the appearance of a conflict of interest.
	I do not participate in the design, manufacture or distribution of any medical device.
	I did not provide consultative services to the Sponsor regarding specific device 510(k) or participate in the preparation of the 510(k).
	I have not performed a 510(k) review where I have a personal relationship with the Sponsor or the application correspondent.

(b)(6)

Rafael Aguila
Product Specialist
February 22nd, 2021

VI. Conflict of Interest Declaration and Certification - *Responsible Third-Party Official*

For the review of the 510(k) submission from:

510(k) Applicant's Name: Laxmi Dental Exports Pvt Ltd.

Device Name: Illusion Aligners

Initials

(b)(6)

I have read and understand Accelerated Device Approval Services' Conflict of Interest and Confidentiality Procedure, regarding conflict of interests and the attachments accompanying the procedure and am aware of my responsibilities under them.

I have not been employed within the last twelve months by the firm who submitted the 510(k) for evaluation.

I did not charge fees contingent or based upon the recommendation for initial classification (SE decision).

I have not performed testing in connection with this specific device 510(k)

I understand that the Accredited Person (AP) program requires that the Accredited Person or any of its personnel involved in 510(k) reviews, which includes those who have authority over the review process, have no ownership or other financial interest in a device manufacturer or distributor that presents the appearance of a conflict of interest.

I do not participate in the design, manufacture or distribution of any medical device.

I did not provide consultative services to the Sponsor regarding specific device 510(k) or participate in the preparation of the 510(k).

I have not performed a 510(k) review where I have a personal relationship with the Sponsor or the application correspondent.

(b)(6)

Rafael Aguila
Responsible Third-Party Official / Owner
April 3rd, 2021

VII. Acceptance review of the 510(k) submission based on the RTA checklist

An acceptance review of the 510(k) submission based on the RTA checklist was made to assess whether the submission is administratively complete and that it includes all of the information necessary for the Third-Party Review Organization to conduct a substantive review on FDA's behalf and for FDA to reach a determination regarding substantial equivalence under section 513(i) of the FD&C Act.

VIII. 510(k) Third Party Review Memorandum

Third Party Organization: Accelerated Device Approval Services, LLC

Signature: (b)(6) Date: February 22nd, 2021

Print Name: Rafael Aguila Title: Product Specialist

Signature: (b)(6) Date: February 23rd, 2021

Print Name: Konrad Kobel Title: Final Reviewer

510(k) Applicant's Name: Laxmi Dental Exports Pvt Ltd.

Device Name: Illusion Aligners

Contact Person: Sameerl Merchant

Table of Contents

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APPENDIX A

Additional Information request and responses

Additional Information request for LAXMI

Accelerated Device Approval Services
1030 15th Street NW
Washington, DC 20005
USA

Dated: November 21, 2020

The Third-Party Reviewer has reviewed your 510(k) submission and has determined that additional information is required. Therefore, your 510(k) is placed on hold, pending a complete response to the following deficiencies.

You should write your responses below each Additional Information request, which should be copied in full. In case you must revise your 510(k) application to include additional documentation or writing, please write in your response letter the location of the changes in the revised 510(k) application.

Also, it is recommended to write in a different color (such as red) any additional wording or sentences in the revised 510(k), to highlight what exactly has been added when compared to the original 510(k) application.

MAJOR DEFICIENCIES

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Appendix 510K Summary

510(k) Summary

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Appendix Section 8- Biocompatibility

Section 8 - Biocompatibility

Illusion Aligners are classified in accordance with ISO 10993-1 as follows:

• Nature of Body Contact: Surface Device, Intact Skin

• Contact Permanent: C – Prolonged (>30days)

Material Biocompatibility – (b)(4) **Polyethylene terephthalate glycol (PETG),** (b)(4)

Line	Standard	Title	Report Reference	Date	Pass/Fail	Page No
1	ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro **cytotoxicity**	(b)(4)	04/25/19	(b)(4)	70
2	ISO 10993-10:2010	Biological Evaluation of Medical Devices- Tests for **Irritation** and Skin Sensitization		05/02/19		94
3	ISO 10993-10:2010	Biological Evaluation of Medical Devices- Tests for Irritation and **Skin Sensitization** (Guinea Pig Maximization Test)		05/29/19		122

(b)(4)

Memorandum to Illusion Aligner Design History File:

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Appendix PETG Paper

Materials (Basel). 2020 May; 13(10): 2386.
Published online 2020 May 22. doi: 10.3390/ma13102386
PMCID: PMC7287673
PMID: 32455913

Thermoplastic Disks Used for Commercial Orthodontic Aligners: Complete Physicochemical and Mechanical Characterization

Valeria Daniele,[1] Ludovico Macera,[1,*] Giuliana Taglieri,[1] Alessandra Di Giambattista,[1] Giuseppe Spagnoli,[1] Alessandra Massaria,[2] Massimo Messori,[3] Enrico Quagliarini,[4] Gianluca Chiappini,[5] Vincenzo Campanella,[6] Stefano Mummolo,[2] Enrico Marchetti,[2] Giuseppe Marzo,[2] and Vincenzo Quinzi[2]

Author information Article notes Copyright and License information Disclaimer
This article has been cited by other articles in PMC.

Associated Data

Supplementary Materials
Go to:

Abstract

Invisible orthodontic aligners (IOAs) have been introduced in the orthodontic field as an innovative alternative for fixed brackets, in relation to their ability to be easily inserted/removed from the oral cavity without affecting the chewing ability and the aesthetic of the patients. The paper provides a complete physicochemical and mechanical characterization of thermoplastic materials in the form of disks used for commercial IOAs. A wide palette of specific techniques is considered, from tensile tests and dynamic-mechanical analysis, to X-Ray diffraction (XRD), differential scanning calorimetry (DSC), Fourier transformation infrared spectroscopy (FTIR-ATR) analyses and water absorption tests. The disks are investigated before and after immersion into staining beverages (red wine, coffee, nicotine and artificial saliva), in terms of colour variations, transparency, and microscopic surface modifications by means of colorimetry, UV-VIS absorbance and scanning electron microscopy (SEM). Among all the samples, polyurethane (PU) exhibited the highest crystallinity and the highest values of mechanical and thermal resistance, while the poly(ethylene terephthalate)-glycol (PETG) samples presented better transparency and less ability to absorb water.

Moreover, red wine and coffee give noticeable colour variations after 14 days of immersion, together with a slight reduction of transparency.

Keywords: thermoplastic materials, invisible orthodontic appliances, physicochemical characterization, mechanical properties, colour change evaluations, water absorption behaviour
Go to:

1. Introduction

With an increase in the demand for adult orthodontics, the demand for invisible orthodontic appliances (IOAs) that can replace the commonly used metal brackets is also increasing [1]. Conventional orthodontic brackets frequently increase the risk of carious lesions and cause gingivitis and periodontitis because of surrounding plaque accumulation [2]. This results in impaired oral health in addition to poor aesthetics during orthodontic treatment [3]. To remedy this problem, invisible orthodontic aligners (IOAs) have been introduced as alternatives for fixed brackets and wires. Invisible orthodontic appliances can be easily inserted and removed and do not affect the chewing ability of the patient [4]. Tooth movement without the use of bands, brackets, or wires was described as early as 1945 by Kesling, who reported the use of a flexible tooth positioning appliance [5,6,7,8]. Subsequently, Sheridan and other researchers developed various types of invisible retainers. Align Technology, Inc. (Santa Clara, CA, USA) introduced the Invisalign system two decades ago, which further developed the principles of Kesling, Nahoum and other researchers using computer-aided design (CAD)/computer-aided manufacturing (CAM) technology combined with laboratory techniques that facilitated the fabrication of a series of dental devices with customized aesthetics that were removable and could move teeth from the beginning to the end [9]. Nevertheless, several thermoplastic materials are considered and the majority of current aligner manufacturers use modified polyethylene terephthalate glycol (PETG) [10,11,12], but comparative analyses that provide useful indications to make decisions based on scientific features are scarce or absent in literature. Considering the ever-growing attention in the dentistry field towards the use of invisible orthodontic aligners, further research on the thermoplastic materials used to manufacture aligners is necessary.

For this task, the present paper aims to provide, for the first time, a complete physicochemical and mechanical characterization of the materials in the form of disks used for the fabrication of IOAs. In particular, the thermoplastic disks here considered are made from two commercial materials, poly(ethylene terephthalate)-glycol (PETG), an analogue/derivative to polyethylene terephthalate (PET), and polyurethane (PU). Among the PETG-based materials, three samples, coming from different brands, are considered in order to evaluate their differences, in terms of degree of crystallinity, optical properties—useful to identify the material with the best characteristics in terms of transparency—and mechanical features in terms of hardness and elastic modulus. Moreover, considering that the exposure of orthodontic materials to staining agents could cause unfavourable and unaesthetic colour changes [13,14,15,16,17], the present paper is also focused on analysing the colour stability of the PETG and PU-based materials, before and after exposure of staining solutions. Finally, the behaviour towards water absorption is investigated at different temperatures, given that the temperature variation plays a fundamental role in the diffusion of water molecules inside the polymeric structure and it is responsible for swelling and mechanical degradation phenomena in the material itself [18,19,20,21,22].

In this regard, the present work gives original and significant analyses in relation not only to the water absorption measurements but also to the solubility of the disks when exposed at high temperature but also at the typical temperature of oral cavity (37 °C). Finally, beside the scientific aspects related to the materials properties, this investigation also presents a useful resource for dentistry operators and manufacturing companies in evaluating and predicting the performance of these products, in addition to the information reported in technical sheets (which are not always readily available before purchasing the products).

Go to:

2. Materials and Methods

2.1. Chemicophysical Characterization of the As-Received Disks

The thermoplastic materials, employed for the realisation of the transparent orthodontic aligners, came from different brands and are characterized by several features in relation to their chemical composition, as reported in Table 1.

Table 1

Main characteristics of the thermoplastic materials used in the present study.

Sample Name	Brand (Manufacturer) *	Chemical Composition
EK	Erkodur (Erkodent Erich Kopp GmbH, Pfalzgrafenweiler, Deutschland)	polyethylene terephthalate glycol (PETG)
EP	Essix Plastic (Dentsply Sirona, York, PA USA)	polyethylene terephthalate (PET)
GA	Ghost Aligner (BART MEDICAL S.r.l., Mezzano, Italy)	polyethylene terephthalate (PET)
ZN	Zendura (Zendura, Bay Materials LLC, Fremont, CA, USA)	polyurethane (PU)

* The manufacture's specification, when available, were reported in [23,24,25].

Before starting the physicochemical characterization, each thermoplastic material available in the form of disk was divided into six equal segments (Figure S1) and each part was characterized by means of different techniques: X-Ray diffraction (XRD), differential scanning calorimetry (DSC), Fourier transformation infrared spectroscopy (FTIR-ATR), UV-visible spectrophotometry and scanning electron microscopy analyses (SEM). In particular, the XRD analysis, performed to establish the degree of crystallinity and the phase composition, was carried out by means of a PANalytical X'Pert PRO (PANalytical Inc., Almelo, Netherlands) diffractometer equipped with a Ni filter (CuKα radiation), in the 5–70° 2θ exploration range and considering a constant steps of 0.026° 2θ (time per step 400 s). XRD patterns were elaborated using a Profile Fit software (HighScorePlus software package, version 4.6a, PANalytical Inc., Almelo, The Netherlands), and

crystalline phases were attributed by ICDD (ICDD, Philadelphia, PA, USA) and ICSD (FIZ Karlsruhe GmbH, Eggenstein-Leopoldshafen, Germany) reference databases.

The thermal characterization analyses (DSC) were performed using a differential scanning calorimeter (Perkin Elmer DSC 8500, PerkinElmer, Waltham, MA, USA), heating the samples in the temperature range −70–240 °C at a rate of 10 °C min^{-1} under a dry nitrogen atmosphere. Then, from the second heating the glass transition temperature (Tg) was determined.

Regarding the Fourier transform infrared spectroscopy (FTIR-ATR), the measurements were performed by using a NexusTM 870 FT-IR spectrophotometer (Thermo Fisher Scientific, Waltham, MA, USA), over a range of 500–4000 cm^{-1} at a resolution of 2 cm^{-1}. The ATR accessory was equipped with a monolithic diamond.

In order to investigate the optical properties of each considered sample, useful to identify the material with the best characteristics in terms of transparency, the absorbance A was measured in the visible light (λ = 300–900 nm) by means of a Lambda 25 Perkin-Elmer ultraviolet/visible spectrophotometer (PerkinElmer, Waltham, MA, USA). The analysis was carried out in transmission, by positioning the disk on the ad hoc polystyrene support perpendicularly to the incident beam. In particular, the presence of the polystyrene support is crucial to collocate the disk in the same position during each analysis, in order to guarantee the transmission by the same area of the disk, so as to control the reproducibility of repeated analyses and to compare data before and after the immersion in the staining aging solutions (Figure 1). This is an important factor to be considered to achieve good and reproducible results, because a very little shift during the measurement corresponds to a great variation of the absorbance value.

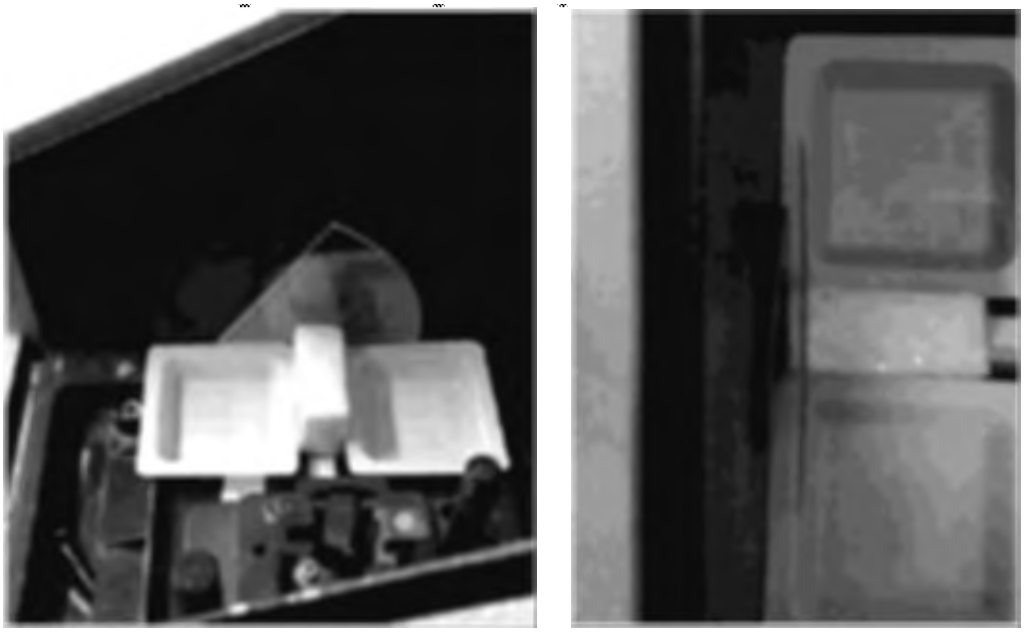

Figure 1

The ad hoc polystyrene support realised to correctly position the sample inside the UV-visible instrument.

2.2. Mechanical Characterization of the As-Received Disks

The tensile test and dynamic-mechanical analysis were performed to characterise the main mechanical properties of the as-received disks by following previous results from literature [11,19,21,26,27,28,29,30] and UNI EN ISO 527-2 [31]. The tensile test was completed using the same thickness as the manufacturer, and the specimens were bone-shaped (geometry 1BA from standard UNI EN ISO 527-2 [31]) and their gauge was 6 mm wide and 30 mm long. The quasi-static tensile tests were conducted by a standard electromechanical machine (model Zwick/Roell® Z050, Zwick Roell, Genova, Italy) imposing a crosshead speed of 5 mm/min [32,33]. The force was measured with a load cell of 5 kN and a high-resolution extensometer for precise measurement of the elongation within the gauge length was used (Figure 2). All tests were conducted at room temperature (about 20 °C).

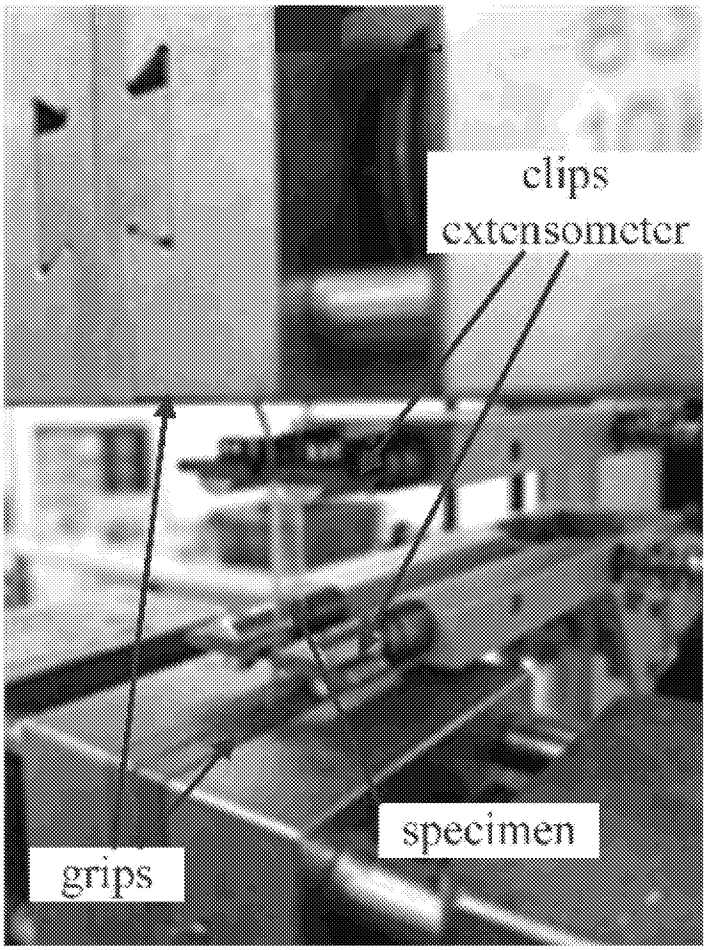

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Figure 2

Representative tensile test on bone-shaped samples.

Dynamic-mechanical analysis was performed by using a TA DMA Q800 analyser (TA Instruments, New Castle, DE, USA) in single cantilever configuration. Tests were carried out from −60 °C to 100 °C with a heating rate of 3 °C min^{-1}, an oscillating frequency of 5 Hz and an applied strain of 0.2%. Due to the presence of frozen molecular orientation deriving from the manufacturing process, all the tested specimens exhibited a significant shrinkage above glass transition temperature (in the range 80–100 °C) which in turn caused the loss of a reliable instrumental signal. For this reason, the analysis was limited to temperatures lower than 100 °C in order to obtain information on the glassy state of the material. The tests were repeated twice on 5 mm × 40 mm specimens, using the same thicknesses as the manufacturer.

2.3. Immersion into Staining Beverages: Colour Change Evaluations.

As the colour stability of orthodontic materials can be unfavourable influenced by staining beverages, subsequently causing aesthetic changes related to the loss of transparency, the aim of this paper is to analyse and compare the colour stability of the materials, before and after the exposure of staining solutions. In particular, the considered samples were immersed into three staining solutions (red wine, coffee and nicotine) and into artificial saliva used to simulate intraoral aging. The staining solutions were prepared as follows: (1) undiluted red wine (San Crispino red wine, Cantine Ronco); (2) 3 g of coffee powder (Nescafè Classic instant coffee) were added in 100 mL of boiling distilled water; (3) the nicotine solution, properly filtered, was obtained by infusing cigarettes filters into distilled water; (4) 120 mL of Oral Balance artificial saliva (Biotène Oral Balance, GlaxoSmithKline Consumer Healthcare S.p.A.) was diluted in 480 mL of deionized water.

Four pieces of thermoplastic discs from each brand were randomly selected and divided into four groups according to the staining solutions. The samples were maintained in immersion up to 14 days in a water bath at T = 37 °C, and subsequently characterized in terms of FTIR-ATR, UV-VIS and colour change. In particular, the colour changes before and after the immersion were evaluated according to the Commission Internationale de l'Eclairage L*a*b* colour system (CIE L*a*b*) [16,34,35], where the parameter L* corresponds to the lightness (+ bright, − dark) while the a* and b* parameters indicates the colour scale from red (+) to green (−) and yellow (+) to blue (−), respectively [34,35]. The colour change values were determined by means of PCE Instrument colourimeter (PCE Deutschland GmbH, Meschede, Germany), before staining (t0) and after 7 and 14 days of immersion (t7 and t14, respectively). All the samples were washed in an ultrasonic bath for 5 min and then dried with paper before starting the measures. The colour measurements were then performed by maintaining physical contact between the vertical tip of the optical sensor and the sample surface. The total colour change (called ΔE*), representing the colour difference before and after staining, was finally calculated according to the equation [34,36]:

$$\Delta E^* = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2} \quad (1)$$

After the measurements, all the data were converted into the national bureau of standards (NBS) system by using the equation NBS = ΔE* × 0.92, in order to describe the levels of perceivable colour change under visual inspection [37,38]. In particular, according to the NBS system, the colour variations can be considered as perceivable if they are higher than 1.5, as reported in Table 2.

Table 2

Description of colour changes from the National bureau of standard units.

National Bureau of Standards Units	Descriptions of Colour Changes	
0.0–0.5	Trace: extremely slight change	
0.5–1.5	Slight: slight change	
1.5–3.0	Noticeable: perceivable	$NBS = 0.92 \times \Delta E^*$
3.0–6.0	Appreciable: marked change	
6.0–12.0	Much: extremely marked change	
12.0 or more	Very much: change to another colour	

2.4. Water Absorption Test at Different Temperatures

Standard tests of water absorption were carried out, according to the International Organization for Standardization, on specimens of the thermoplastic materials [39,40]. In particular, for each manufacturer, three specimens were stored for 14 days at different temperatures (T), as follows: 20 °C ± 1° C, 37 °C ± 1 °C and 70 °C ± 1 °C respectively, in order to evaluate the influence of the temperature on the mechanical cohesion decrease. Then, both the water absorption (Wsp) and the water solubility (Wsl) were calculated by means of the following equations, in accordance with the corresponding ISO:

$$W_{sp} = m_2 - m_3 V$$
$$W_{sl} = m_1 - m_3 V$$

where m_1 is the mass of the disks before the immersion in water, m_2 is the mass during the immersion period up to 14 days and m_3 is the mass after reconditioning and V is the volume of the considered aligner for this test. Two disks for each brand were considered, and the medium value of the obtained results was reported. All the data are expressed in μg/mm^3. Finally, the as-received thermoforming materials, as well as those immersed both in water at different temperatures and in staining beverages, were observed by scanning electron microscopy analyses (SEM, Gemini SEM 500, Zeiss, Oberkochen, Germany), in order to investigate the surface modifications. For this task, the immersed pieces of thermoplastic discs from each brand were cut, chrome coated in a sputter coating unit, and observed at different magnifications.

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3. Results and Discussion

3.1. Chemicophysical and Mechanical Characterization of the Disks

Figure 3 shows the X-ray diffraction patterns of the as-received thermoplastic materials of the different brands.

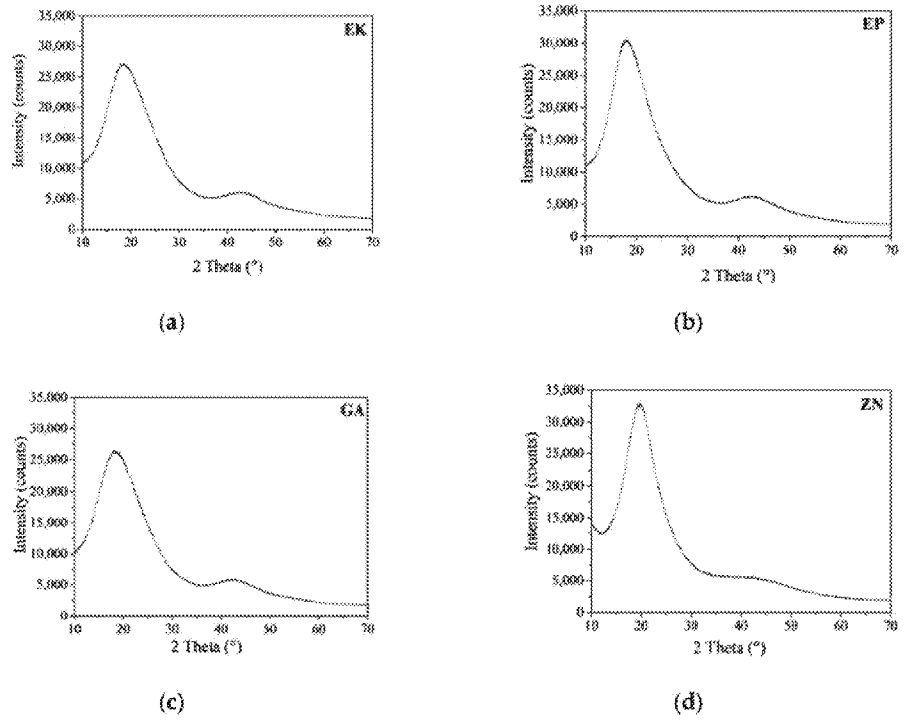

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Figure 3

X-ray diffraction (XRD) spectra of the as-received thermoplastic materials: (**a**) EK; (**b**) EP; (**c**) GA; (**d**) ZN.

It is evident that EK, EP and GA samples have comparable XRD patterns, and this result confirms that they are made up of amorphous PET, the same base polymer also associable with PETG, by the comparison with the ICDD reference database (#00-060-1509) [41,42]. In fact, we observed the presence of two broad diffraction haloes that peaked at around 19° and 43° 2θ, respectively, and that were exactly related to the features of the amorphous PET phase. On the contrary, the ZN sample is composed of a different based-polymer, revealing an XRD pattern characterized by three broad haloes at around 10°, 20° and 43° 2θ, assigned to the scattering from soft polyurethane (PU) chains with regular interplanar spacing [43,44]. In Table 3 the measurement of the full width at half maximum (FWHM) of the Bragg peaks is reported, which allows one to determine the degree of crystallinity of the considered samples. The obtained results reveal that ZN disk presents the lowest FWHM value (corresponding to 6.313° 2θ) among all the samples; EK and GA disks show comparable FWHM values, while EP presents a lower FWHM value, resulting in the highest crystalline material among all the PETGs.

Table 3

Full width at half maximum values (FWHM) of the as-received thermoplastic materials of the different brands.

Sample	EK	EP	GA	ZN

Sample	EK	EP	GA	ZN
FWHM (° 2θ)	9.643	8.148	9.695	6.313

The DSC curves, performed to determine the glass transition temperature (Tg), confirm the XRD results, revealing that all the samples are made by amorphous thermoplastics. Only one thermal phenomenon, corresponding to the Tg, can be recognised (Figure S2). In particular, EK, EP and GA samples are characterized by endothermic peaks having Tg values of 83 °C, 89 °C and 80 °C respectively, corresponding to the typical Tg of PETG polymers. In fact, as reported in literature, PETG is considered an amorphous thermoplastic of commercial PET, having a glass transition temperature of about 80 °C [22,45]. On the contrary, the glass transition temperature of the ZN sample is of about 96 °C, a value different both from the Tg values generally associated with PETG and PU based-polymers. This is probably attributed to the additives present into the polyurethane-based mixtures, as also discussed in a previous literature [46].

The FTIR-ATR analyses on EK, EP and GA samples show comparable profiles with specific bands of PETG (Figure 4) [47,48,49,50,51]. In particular, the following bands are identified: the peak at 1714 cm^{-1} can be ascribed to the C=O of ester groups, and the C-H out-of-plane deformation of two carbonyl substituents on the aromatic ring at 725 cm^{-1}; the two bands at 1410 and 1240 cm^{-1} related to –CH2– deformation and C(O)–O stretching of ester groups, respectively; the asymmetric and symmetric aliphatic C–H stretching vibrations are observed at 2852 and 2926 cm^{-1}, due to the presence of methylene groups in the structure of PETG.

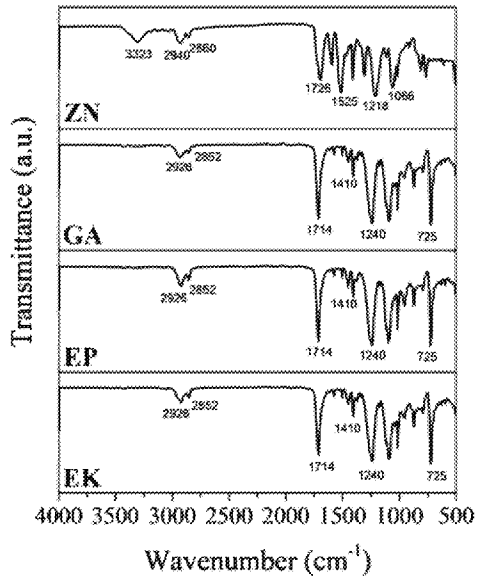

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Figure 4

Fourier transformation infrared spectroscopy (FTIR) spectra of the thermoplastic materials.

In the ZN sample, the IR absorption bands, characteristic of the semirigid PU based-polymer, can be summarized as follows: characteristic bands of the hydroxyl and carbonyl groups in the 3323 and

1726 cm^{-1} regions, respectively; the two bands between 2940 and 2860 cm^{-1} attributed to the symmetric and nonsymmetric stretching of the C–H bond with carbonyl; stretching C = O and N–H bonds around 1700 and 1525 cm^{-1}; band features of the polymerized urethanes [43].

In regard to UV-VIS measures, for all the samples, similar trends are observed, showing a decrease in the absorbance values by increasing the wavenumber (Figure 5). It is possible to note that the untreated PETG-based disks show similar absorbance curves in the visible range, clearly lower than the PU-based disk. These results underline the lower transparency of the ZN disk when compared to the others, as also confirmed by visual inspections. Moreover, considering that the transparencies are related inversely to the degree of crystallinity [52], the UV-VIS results confirm the XRD measurements that reveal the highest degree of crystallinity in ZN sample.

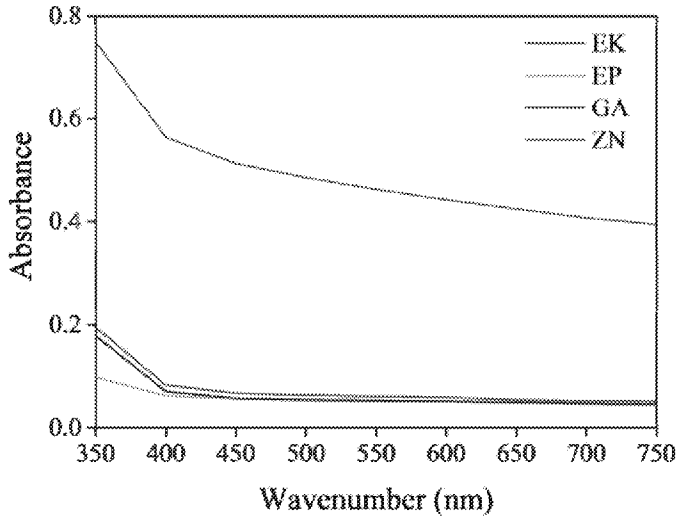

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Figure 5

Absorbance curves of the as-received thermoplastic materials; EK sample (red line), EP sample (green line), GA sample (black line), ZN sample (blue line).

3.2. Mechanical Characterization

The experimental curve stress—strain of the tensile tests performed are reported in Figure S3 for each material. Three tests were carried out for each material, and the figure shows the whole curve and a zoom in the initial elastic zone. A comparison of the tensile curves for the four materials is shown in Figure 6, and in Table 4, the characteristic mechanical parameters calculated according to the standard UNI EN ISO 527-1 are reported. m is the maximum stress reached during the test; εm is the strain at maximum stress; εtb is the strain at break and the maximum elongation; and E is the elastic modulus calculated as the slope of the curve between 0.05% and 0.25% of the deformation. The measured values exhibit a low standard deviation showing a good repeatability of the tests.

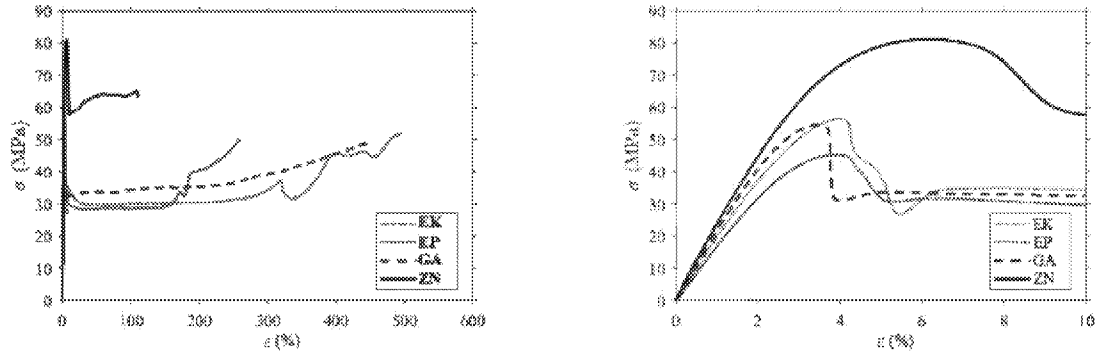

Figure 6

Comparison of the experimental stress–strain curves (**a**) until break; (**b**) a magnification in the elastic and post-peak phase.

Table 4

Mechanical parameters calculated according to the standard UNI EN ISO 527-1: σ_m is the maximum stress, εm is the strain at maximum stress, εtb is the strain at break and E is the elastic modulus. μ is the mean value, σ is the standard deviation and C_v is the coefficient of variation.

Sample	σ_m (MPa)			ε_m (%)			ε_{tb} (%)			E (MPa)		
	μ	σ	c_v	μ	σ	c_v	μ	σ	c_v	μ	σ	c_v
EK	55.93	0.42	0.8%	3.99%	0.13%	3.3%	507%	59%	11.6%	1933.03	130	6.7%
EP	45.37	0.54	1.2%	3.91%	0.02%	0.4%	261%	5%	1.8%	1742.03	46	2.6%
GA	53.65	0.85	1.6%	3.32%	0.15%	4.5%	396%	58%	14.7%	2102.83	24	1.1%
ZN	78.20	5.25	6.7%	6.22%	0.05%	0.8%	95%	30%	31.7%	2489.43	74	3.0%

The characteristic mechanical parameters (the maximum stress, the strain at maximum stress, the strain at break and E the elastic modulus) calculated from the tensile test are compatible with typical values of PET and PU polymers. ZN samples exhibit the highest average values for the elastic modulus (2.49 GPa) and for the maximum stress (78 MPa) but have the lowest strain at break (95%). The three PETGs have comparable values, and the EP has the lowest modulus of elasticity (1.74 GPa) and the lowest maximum stress (45 MPa).

Representative storage modulus (E') vs. temperature curves are reported in Figure 7. Storage modulus values at room temperature (E'RT) and glass transition temperature values (Tgonset, determined as onset at the of the E' curve drop) are reported in Table 5.

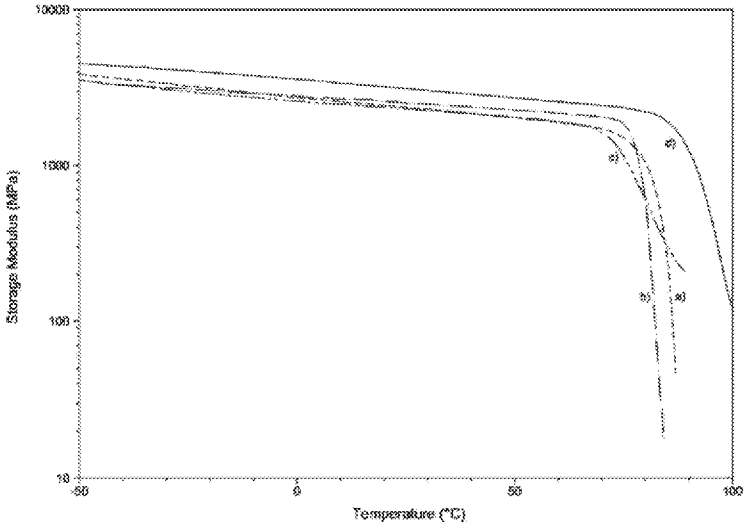

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Figure 7

Representative storage modulus as a function of temperature: (**a**) EK, (**b**) EP, (**c**) GA, (**d**) ZN.

Table 5

Dynamic-mechanical analysis: Storage modulus at room temperature (E'RT) and glass transition temperature (Tgonset, determined as onset at the of the E' curve drop).

Sample	EK	EP	GA	ZN
E'_{RT} (MPa)	2430	2160	2280	2840
Tg_{onset} (°C)	77.2	79.5	71.9	88.1

The values of glass transition temperature detected by dynamic-mechanical analysis (Tgonset) are in good agreement with those obtained by DSC analysis, showing a slightly lower Tgonset for PETG-based samples (71.9 °C, 77.2 °C and 79.5 °C for GA, EK and EP, respectively) when compared with PU-based samples (88.1 °C for ZN). The highest Tg value showed by ZN also results in the highest value of storage modulus E'RT (2840 MPa). The dynamic modulus values for PETG-based samples are in the range 2160–2430 MPa and are compatible with typical value for rigid amorphous thermoplastic polymers. Taking into account the experimental error and the different mechanical analysis (quasi-static and oscillatory conditions), the storage modulus values are also in good agreement with the elastic modulus values reported in Table 4.

3.3. Colour Change Evaluations

The visual inspections of the disks of thermoplastic materials of the different brands before and after 14 days of immersion in the staining solutions are shown in Figure 8. For all the samples, the colour variations, as perceivable to the naked eye, were observed only when the samples are immersed in red wine or coffee, showing colours of pink and light brown, respectively.

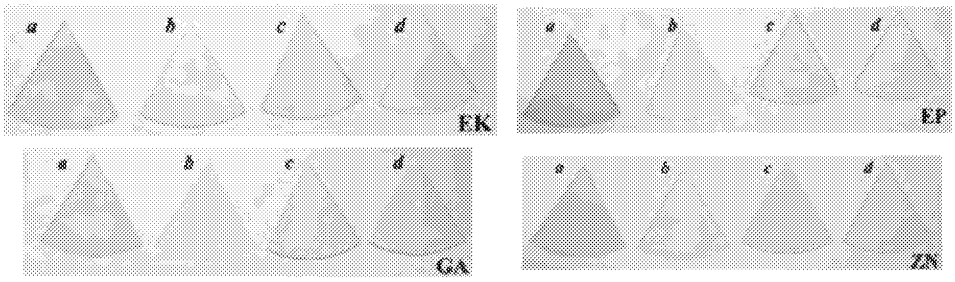

Figure 8

Visual inspection of the thermoplastic materials of the different brands, before and after 14 days of immersion both in artificial saliva and staining beverages. Legend: **a**: red wine; **b**: artificial saliva; **c**: coffee; **d**: nicotine solution.

These results are confirmed and quantified by the colorimetric measurements, reported in Figure 9. According to the descriptions of colour changes established by the NBS system (Table 2), all the samples, maintained up to 7 days in immersion, reveal NBS values ranging from an extremely slight colour change (NBS < 0.5) to a slight change (NBS < 1.5), except for the immersion in the coffee solution. In this latter case, EP, GA and ZN samples show a perceivable colour variation (NBS < 3), while the EK sample displays marked change in the colour (NBS > 3).

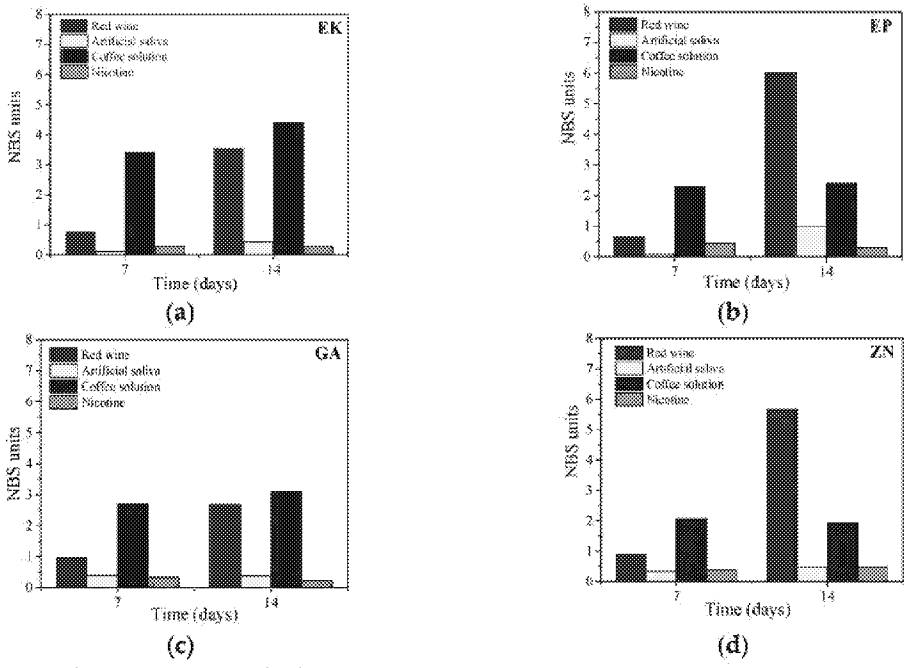

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Figure 9

Colorimetric measurements (expressed by NBS system) of the thermoplastic disks after immersion in staining beverages for 7 and 14 days, respectively (**a**) EK, (**b**) EP, (**c**) GA, (**d**) ZN.

After 14 days of immersion in the nicotine solution, all the samples exhibited only slight colour changes, while when immersed in red wine, they revealed perceivable colour variations, with an increase with time, especially for EP and ZN (NBS > 3). Finally, considering the immersion in coffee solutions, marked changes in colour were observed in the EK sample, while the other disks presented only perceivable variations with NBS values ranging from 1.5 to 3.0.

In regard to the UV-visible measurements, the absorbance curves of the thermoplastic disks of the different brands before and after 14 days of immersion in beverage solutions are reported in Figure 10. In particular, in order to directly compare the different behaviour of brands and solutions, the graphs are characterized by the same y-scale.

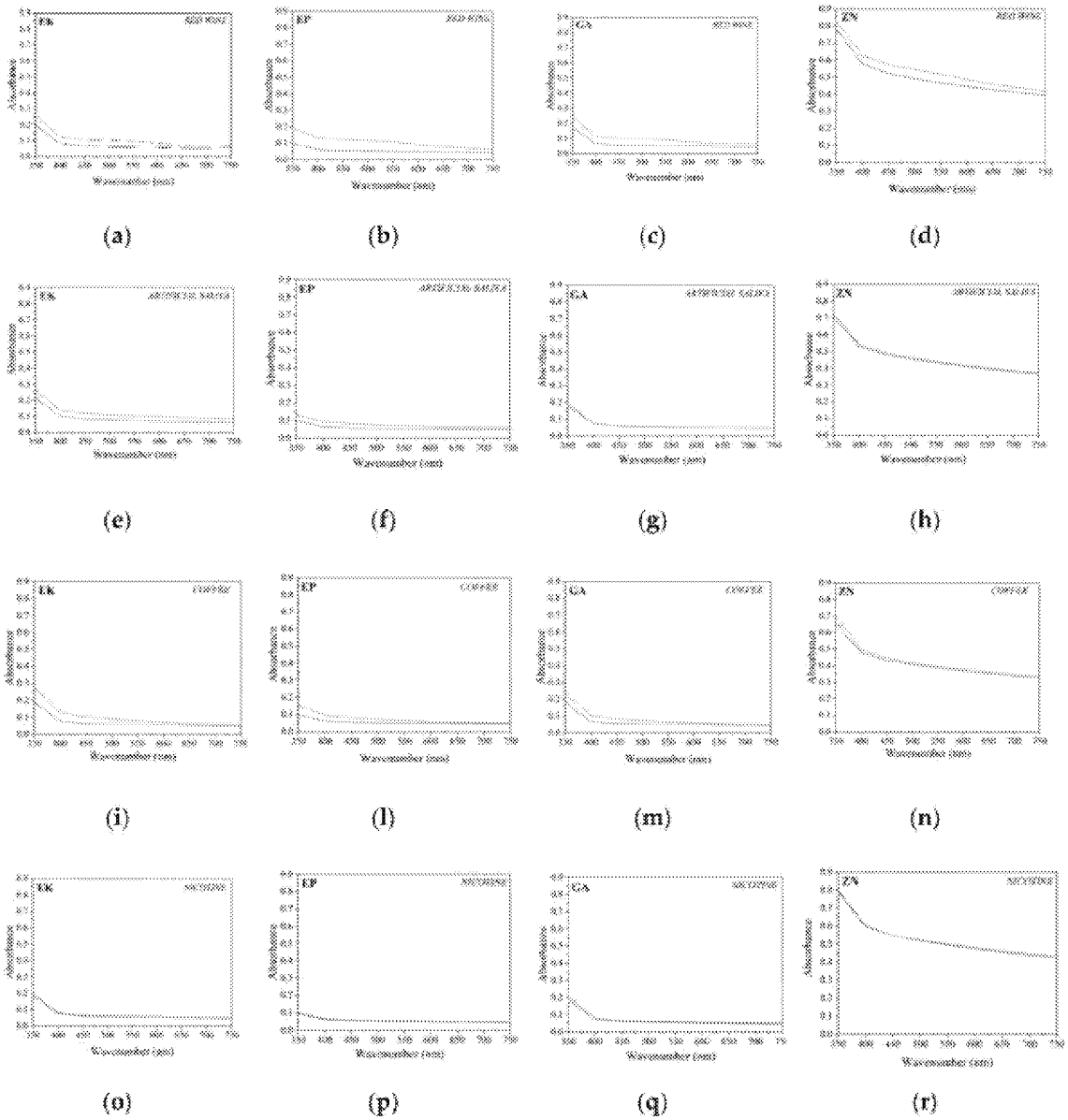

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Figure 10

Comparison of absorbance curves of the thermoplastic disks before (black line) and after (red line) 14 days of immersion into staining agents. (**a**–**d**) red wine (EK, EP, GA and ZN samples, respectively); (**e**–**h**) artificial saliva (EK, EP, GA and ZN samples, respectively); (**i**–**n**) coffee (EK, EP, GA and ZN samples, respectively); (**o**–**r**) nicotine solution (EK, EP, GA and ZN samples, respectively).

For all the samples independent from the staining agent, it is possible to note a general increase in the absorbance curves, resulting in a small loss of transparency of all the samples. In particular, for the PETG-based aligners, (EK, EP and GA samples), similar behaviours were observed, and in particular, an absorbance increase of about 30% for all the analysed wavelengths was measured after immersion in red wine and coffee. On the contrary, regarding the results for ZN samples, smaller increases in the absorbance were registered, confirming the visual observations previously reported (Figure 8).

3.4. Water Absorption Properties

In regard to the study of the influence of temperature on water absorption of the disks versus time, the curves are reported in Figure 11.

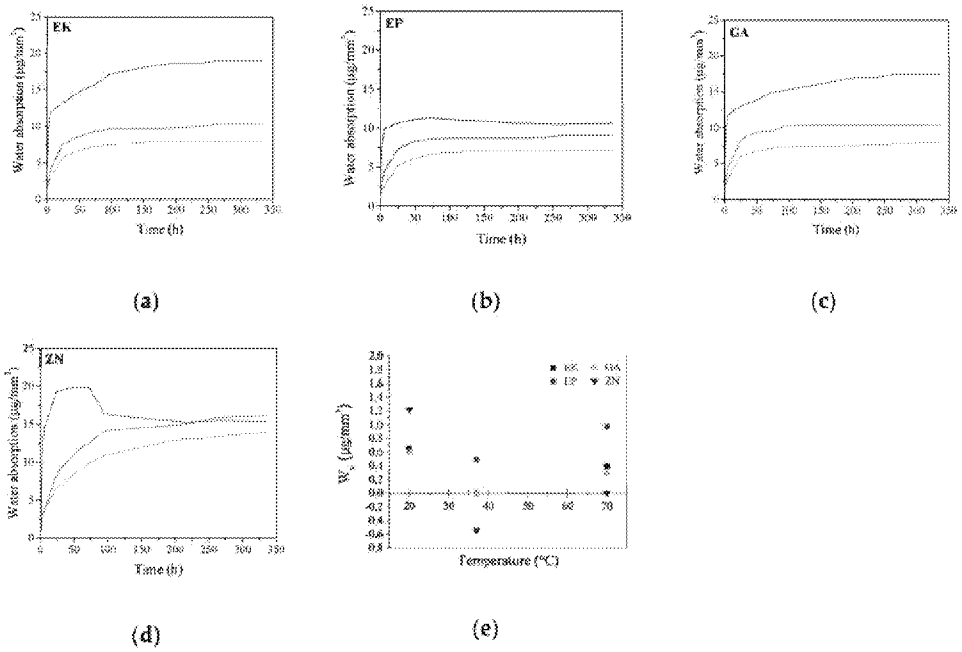

Figure 11

(**a**–**d**) Water absorption curves of the different samples by varying both the immersion time and temperatures. Legend: T = 20 °C (black line); T = 37 °C (red line); T = 70 °C (blue line). (**e**) Nominal water solubility of the samples (Wsl), after immersion in water at different temperatures.

Considering the samples immersed in water at T = 20 °C, it is possible to note that all PETG-based disks (EK, EP and GA) present comparable trends reaching a hyperbolic saturation value of water absorption of about 8 μg/mm^3. On the contrary, the curve of the PU polymer (ZN sample) does not

reach a plateau in the considered time interval showing, in addition, the highest water absorption value among all the samples (up to 14 μg/mm^3). The obtained results can be related to the different chemical composition of the two groups of the considered samples, causing different behaviour in the penetration of water molecules into the material structure. Considering that the penetration of water in the polymeric disk is responsible for swelling and mechanical degradation phenomena, which in turn leads to physicochemical changes in the material itself [19,20,21], these results could be very important because the degradation will be more evident when increasing the water absorption ability of the material itself.

Considering the immersion in water at 37 °C, all the curves show similar trends in respect to those obtained at 20 °C. Nevertheless, it is possible to note that the samples generally reach higher saturation values ranging from about 10 to 16 μg/mm^3 for PETG- and PU-based polymers, respectively, due to the role of temperature on the higher diffusion of water molecules inside the materials. After the immersion in water at 70 °C, PETG-based disks reveal an increase in the water absorption, particularly evident for the EK and GA samples, which reach final values of about 17 μg/mm^3. On the contrary, ZN presents an initial increase in the amount of water absorbed, reaching the maximum value within the first 75 h of immersion. Subsequently, the curve shows a decrease in the absorbed water of up to about 15 μg/mm^3. This decrease in weight could be related to a loss of polymer molecules with time; if this hypothesis was true, the effective amount of water absorbed should be about 20 μg/mm^3, corresponding to the hyperbolic saturation behaviour.

In parallel, in regard to the Wsl results, the obtained data are reported in Figure 11e. We can observe that at 20 °C, all the samples reveal a positive Wsl that is a variation in weight after the immersion, which is likely due to absorbance of water rather than real solubilisation of the material. In particular, the ZN sample shows the highest values (1,22 μg/mm^3) followed by EK, EP and GA (with 0.66, 0.60 and 0.59 μg/mm^3, respectively). When increasing the temperature up to 37 °C, that is, the temperature relivable in the oral cavity, the EP sample reveals less variation in weight (observed as 20 °C (Wsl of 0.5 μg/mm^3)), while the EK and GA samples present values of next to 0 μg/mm^3, underlining a material loss, particularly evident for the ZN sample showing negative values as well. These results can be justified considering that the remaining water was probably trapped inside the samples after immersion, entering the polymeric lattice in an irreversible way and causing modification of the properties of the material itself. Finally, after the immersion at 70 °C, the Wsl values increase for all the samples, confirming that they are strictly related to the balance between the real solubility of the material and its ability to absorb water during the test.

In conclusion, the results obtained from the water absorption test underline that the temperature, also at relatively low values (37 °C), is a critical factor both on the diffusion of water inside the material and in the thermal degradation of the polymer itself, weakening and breaking the bonds between the chains and causing possible degradation with time in terms of mechanical properties.

From the visual observations, after the immersion at 20 °C and 37 °C, all the samples remain unaltered. On the contrary, when immersed at 70 °C, they present clear changes visible to naked eye after just 1 h from the beginning of the immersion tests (Figures S4 and S5). In particular, EK sample tends to bend and show a visible change in colour, turning from transparent to white in 6 days (Figure S4b). Additionally, after 6 days of immersion, the presence of bubbles and microcracks on the disk surface is evident, probably due to the increase in the amount of water entering the sample, as discussed before. The same results are obtained from the EP sample, showing a loss of

transparency together with the formation of superficial bubbles that after 6 days of immersion at 70 °C (Figure S4c,d). The GA sample shows a clear mechanical deformation after just 15 min from the beginning of the test (Figure S5a), reaching a colour variation from transparent to white combined with the formation of superficial bubbles after 6 days of immersion (Figure S5b). From the visual inspection of the ZN disk, a higher stiffness in terms of mechanical deformation is evident, showing only slight curvatures after 15 min of immersion, which remain unaltered until the end of the test (Figure S5d). Moreover, ZN samples do not reveal chromatic variations in colour, indicating a lower degradation of this polymer compared to the other brands when exposed to high temperatures.

SEM images related to the samples disks as received, at two different magnifications, are shown in Figure 12. At a higher magnification, the surface of the EK sample (Figure 12a–e) appears rather smooth with small and sporadic superficial impurities or irregularities and ununiformly distributed. The EP and GA samples are characterized by a smooth surface too, but differently from what was observed in the EK sample, they present a larger number of impurities or irregularities on their surfaces (Figure 12b–f). However, in the case of the EP sample, such irregularities are in relief and characterized by a circular morphology, particularly evident at high magnification, with typical dimensions ranging from 5 to 50 μm. Finally, in regard to the polyurethane-based disk, the ZN sample surface presents rare impurities, but differently from what was observed in all the PETG-based disks, it appears wrinkled (particularly visible at high magnification) and is characterized by some small cavities (Figure 12d–h).

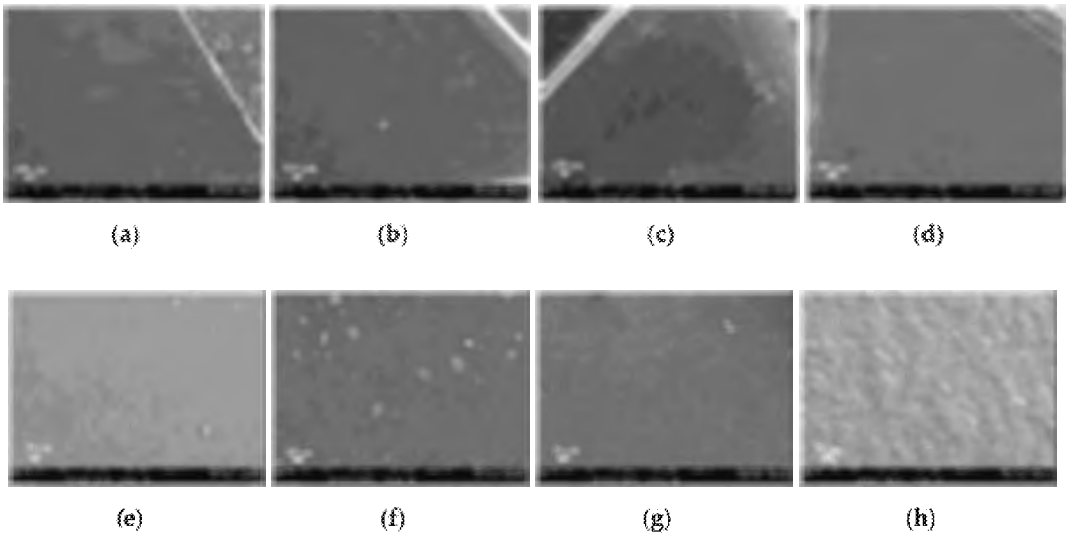

Figure 12

Scanning electron microscopy (SEM) micrographs of the samples, as received: (**a**–**e**) EK disk (magnifications 80× and 500×, respectively); (**b**–**f**) EP disk (magnifications 80× and 500×, respectively); (**c**–**g**) GA disk (magnifications 80× and 500×, respectively); (**d**–**h**) ZN disk (magnifications 80× and 500×, respectively).

When immersed in water at different temperatures, all the samples show variations in the surface features, already evident at 37 °C. Specifically, after the immersion for 14 days at 37 °C, a general increase in the amount of impurities and raised irregularities is observed on the PETG-based samples (Figure 13a–c). Moreover, several ripples are recognizable too in the EP sample (Figure

13b–f) that are not visible in the as-received disk. Furthermore, the ZN sample reveals an increase in the irregularities present on its surface, together with a reduction in the wrinkled morphology, Figure 13d–h.

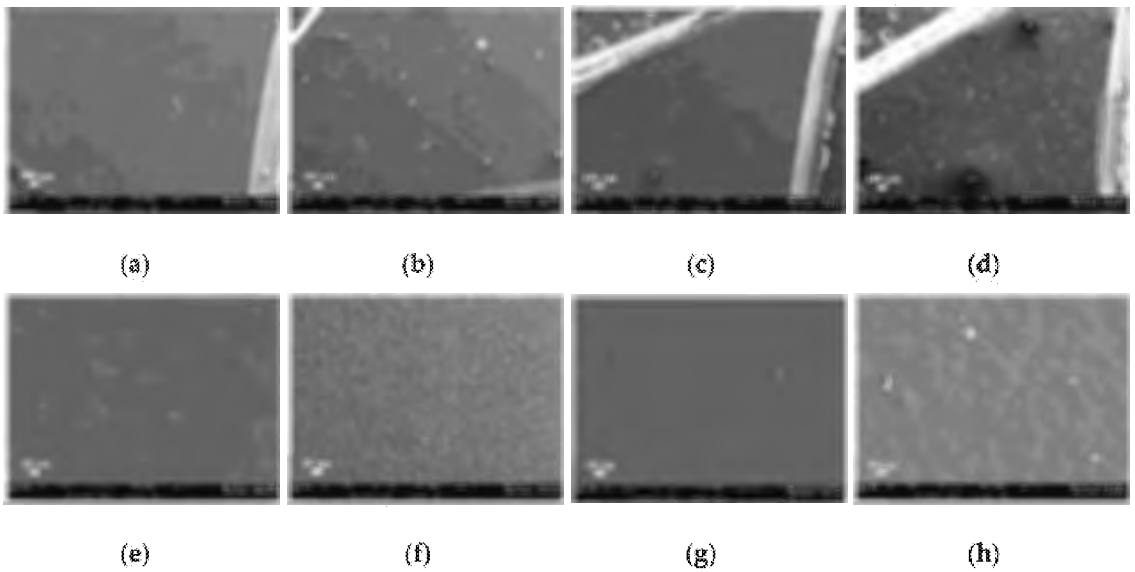

Figure 13

SEM micrographs of the samples immersed in water at 37 °C: (**a**–**e**) EK disk (magnifications 80× and 500×, respectively); (**b**–**f**) EP disk (magnifications 80× and 500×, respectively); (**c**–**g**) GA disk (magnifications 80× and 500×, respectively); (**d**–**h**) ZN disk (magnifications 80× and 500×, respectively).

Considering the images of the samples immersed in water at 70 °C, EK and GA disks remain similar, presenting large bubbles together with the formation of localized cavities, (Figure 14a–e,c–g, respectively). The EP sample shows noticeable superficial changes with the formation of several microbubbles, cavities and a high number of impurities, homogeneously distributed and characterized by an irregular morphology (Figure 14b–f). Finally, large bends, parallel placed and homogenously distributed, appear on the surface of the ZN sample; on these bends all the impurities and irregularities seem to be localized (Figure 14d). At higher magnification, the surface after immersion at 70 °C always appears smooth, (Figure 14h), when compared to those observed at lower temperatures, which is in agreement with the ability of water to be absorbed inside the polymeric structure causing the swelling phenomena. Both the results on the PETG-based disks and on the PU-based one can be related to the polymer degradation caused by the simultaneous action of temperature, as also reported in the literature [22].

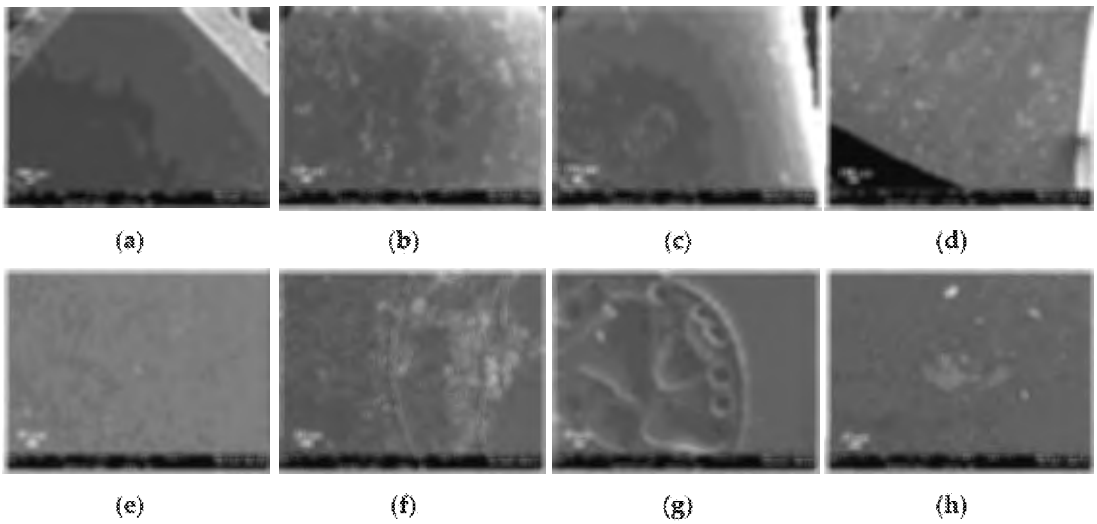

Figure 14

SEM micrographs of the samples immersed in water at 70 °C: (**a**–**e**) EK disk (magnifications 80× and 500×, respectively); (**b**–**f**) EP disk (magnifications 80× and 500×, respectively); (**c**–**g**) GA disk (magnifications 80× and 500×, respectively); (**d**–**h**) ZN disk (magnifications 80× and 500×, respectively).

From the comparative analyses carried out in this work, the PETG disks present small differences when exposed to the same external conditions, despite the differences in cost they have on the market. On the contrary, the polyurethane disk, regardless of its advantageous mechanical and thermal resistance, showed a limited transparency, and when immersed in water, a great ability to absorb water and to release small quantities of product by increasing temperature.

In conclusion, this paper represents a detailed guide which can be used, in addition to the manufacturers' technical sheets, for a more appropriate choice of materials to use to realise clear orthodontic aligners, taking into account all the aspects and features from the mechanical to the physicochemical point of view. Furthermore, this paper can be the basis for further in-depth studies on these materials or for innovative materials to be used in the orthodontic field.

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4. Conclusions

This paper aims to provide an overview on the physicochemical and mechanical characterization of thermoplastic disks used to realise orthodontic invisible aligners. Disks from different brands are considered based on the most used polymeric materials, PETG (EK, EP and GA brands) and PU (ZN brand). The analyses reveal that the PU disk presents the highest crystallinity as well as the highest mechanical strength and glass transition temperature among all the samples. Instead, all the PETG-based disks are characterized by similar crystallinity, mechanical resistance and thermal stability. From UV-VIS measurements, the PETG disks show similar absorbance curves, and they present lower values in comparison with the PU disk, underlining a better transparency, as also confirmed by visual inspections and crystallinity values. The immersions in staining beverages reveal that red wine and coffee solutions give the highest colour variations, while nicotine and

artificial saliva show negligible colour variations. Overall, the GA disk presents colour alterations lower than the other disks, as confirmed by the UV-VIS analyses performed after staining beverages immersions.

In regard to the water absorption ability versus time, all the PETG disks present a trend of hyperbolic saturation that increases with temperature and with an amount of absorbed water at 37 °C of about 8 $\mu g/mm^3$. Specifically, the EP sample reveals the lowest ability to absorb water with increasing temperature. On the contrary, the PU disk presents not only higher amounts of absorbed water (15 $\mu g/mm^3$ at 37 °C), but also a different trend in the saturation behaviour at 70 °C, revealing a possible small dissolution in the liquid phase. In this respect, as shown from the nominal water solubilities measurements, the EP disk presents the lowest dissolution aptitude. This result could provide important information because the penetration of water causes swelling and mechanical degradation phenomena, so a high-water absorption ability corresponds to a higher aptitude to degradation of the material itself. SEM observations confirm the swelling phenomena, more evident in the surface of the PU sample that changes from a wrinkled to a rather smooth appearance with increasing temperature.

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Supplementary Materials

The following are available online at https://www.mdpi.com/1996-1944/13/10/2386/s1, Figure S1: The as-received thermoplastic materials properly cut into six equal segments, Figure S2: DSC results for (a) EK, (b) EP, (c) GA, (d) ZN thermoplastic materials, respectively, Figure S3: Experimental stress-strain curves: (a-b) EK, (c-d) EP, (e-f) GA, (g-h) ZN, Figure S4: Visual observations of EK and EP samples after immersion in water at 70°C: (a-c) comparison between the as-received sample (left) and the disk immersed for 1 hour (right); (b-d) samples after 6 days of immersion, Figure S5: Visual observations of GA and ZN samples after immersion in water at 70°C: (a-c) comparison between the as-received sample (left) and the disk immersed for 15 minutes (right), respectively; (b-d) samples after 6 days of immersion.

Click here for additional data file.(639K, pdf)

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Author Contributions

Conceptualization, V.D., G.T., V.Q. and G.M.; Methodology, V.D, G.T., V.Q. and E.Q.; Validation, V.D. and G.T.; Investigation, V.D., A.D.G., L.M., G.S., A.M., M.M., E.Q. and G.C.; Data Curation, V.D., A.D.G., L.M., G.S., A.M., M.M., E.Q. and G.C.; Writing-Original Draft Preparation, V.D., G.T. and A.D.G.; Writing-Review & Editing, V.D., G.T., L.M., E.Q. and V.Q.; Visualization, V.D., L.M., G.T., A.D.G., G.S., A.M., M.M., E.Q., G.C., V.C., S.M., E.M., G.M. and V.Q.; Supervision, V.D., G.T., V.Q., E.Q. and G.M.; All authors have read and agreed to the published version of the manuscript.

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Conflicts of Interest

The authors declare no conflict of interest. The founding sponsors had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, and in the decision to publish the results.

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Date: 01.15.21

To: Rafael Aguila – Accelerated Device Approval Services

From: Robert O. Dean – Compliance Systems International LLC.

Subject: Laxmi Illusion Aligners – Reply to Rafael Aguila – Accelerated Device Approval Services email dated 01.12.21

Dear Rafael,

(b)(4)

Kind regards,

Robert O. Dean

Compliance Systems International LLC.

(b)(4)

(b)(4)

From: Stephens, Nicholas * [Nicholas.Stephens@fda.hhs.gov]
Sent: 4/5/2021 4:42:19 PM
To: support@510k-review.com
Subject: K211010 Acknowledgement Notification
Attachments: K211010- Letter.pdf

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Acknowledgment Letter

4/5/2021

Rafael Aguila, Responsible Third-Party Official
Accelerated Device Approval Services
6800 S.W. 40th Street, Ste. 403
Ludlum, FL 33155
UNITED STATES

Dear Rafael Aguila:

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Submission Number: K211010
Received: 4/5/2021
Applicant: Laxmi Dental Exports Pvt Ltd
Device: Illusion Aligners

We will notify you when the review of this document has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

Illusion Aligners 510K

Section 1 - CDRH Premarket Review Submission Cover Sheet

Section 1 - CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: June 30, 2023
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
November 11, 2020		

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submission Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Laxmi Dental Exports Pvt Ltd	3004793836		
Division Name *(if applicable)*	**Phone Number** *(including area code)*		
	0091 9820268438		
Street Address	**FAX Number** *(including area code)*		
Survey No. 201/1, Village Gundale, Boisar Chillar Highway			
City	**State / Province**	**ZIP/Postal Code**	**Country**
Boisar	District – Palghar	401501	India
Contact Name			
Sameer Merchant			
Contact Title	**Contact E-mail Address**		
CEO	sameer@laxmidental.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Compliance Systems International, LLC			
Division Name *(if applicable)*	**Phone Number** *(including area code)*		
	718-440-7362		
Street Address	**FAX Number** *(including area code)*		
1083 Delaware Ave			
City	**State / Province**	**ZIP Code**	**Country**
Buffalo	NY	14223	USA
Contact Name			
Robert O. Dean			
Contact Title	**Contact E-mail Address**		
President	(b)(6)		

FORM FDA 3514 (6/20) Page 1 of 5 Pages

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SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence.

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	NXC	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K173784	Smylto Invisible Clear Aligners	Smylto, Inc
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Aligner Sequential

	Trade or Proprietary or Model Name for This Device	Model Number
1	Illusion Aligners	N/A
2		
3		
4		
5		

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	None	2		3		4		5		6	
7		8		9		10		11		12	

Data Included in Submission

- [ ] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
NXC	21CFR872.5470	[ ] Class I [x] Class II
		[ ] Class III [ ] Unclassified

Classification Panel

Dental

Indications *(from labeling)*

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

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number *(if known)*:

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number:

☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name: Laxmi Dental Exports Pvt Ltd	Establishment Registration Number: 3004793836
Division Name *(if applicable)*:	Phone Number *(including area code)*: 0091 9820268438
Street Address: Survey No. 201/1, Village Gumtale, Boisar Chillar Highway	FAX Number *(including area code)*:
City: Boisar	State / Province: District – Palghar; ZIP Code: 401501; Country: India
Contact Name: Sameer Merchant	Contact Title: CEO; Contact E-mail Address: sameer@laxmidental.com

☐ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number:

☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name:	Establishment Registration Number:
Division Name *(if applicable)*:	Phone Number *(including area code)*:
Street Address:	FAX Number *(including area code)*:
City:	State / Province: ; ZIP Code: ; Country:
Contact Name:	Contact Title: ; Contact E-mail Address:

☐ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number:

☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name:	Establishment Registration Number:
Division Name *(if applicable)*:	Phone Number *(including area code)*:
Street Address:	FAX Number *(including area code)*:
City:	State / Province: ; ZIP Code: ; Country:
Contact Name:	Contact Title: ; Contact E-mail Address:

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	10993-2009(E)	ISO	Biological Evaluation of Medical Devices - Part 5, Tests for in vitro Cytotoxicity	2009(E)	06/01/2009
2	10993-10:2010 (E)	ISO	Biological Evaluation of Medical Devices - Part 10, Tests for Irritation and Skin Sensitization.	2010(E)	08/01/2010
3	ISO 10993-10:2010 (E)	ISO	Biological Evaluation of Medical Devices - Part 10, Tests for Irritation and Skin Sensitization.	2010(E)	08/01/2010
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Section 2 - 510K Cover Letter

Section 2 - Cover Letter

LAXMI DENTAL LAB USA INC.
100 Hollister Rd, Unit 1, Teterboro, NJ 07608 1.855.go.laxmi

Food and Drug Administration
Center for Devices and Radiological Health (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Subject: Premarket Notification Submission – 510(k) Traditional, Illusion Aligners

To whom it may concern;

Laxmi Dental Lab USA, Inc is submitting the enclosed Premarket Notification, 510(k) for Illusion Aligners, prepared and formatted in accordance with 21CFR807.

- Proprietary Trade Name: Illusions Aligners
- Common Name: Orthodontic Tray Aligner
- Condition: Non-Sterile
- Classification Name: aligner, sequential
- Establishment Registration Number: 3009432549
- Class: II
- Panel: Dental
- Code: NXC
- Regulation: 21CFR872.5470
- Predicate medical device: K173784, Smylio Invisible Clear Aligners
- Manufacturer: Laxmi Dental Exports Pvt Ltd., Survey No. 201/1, Village Gundale, Boisar Chillar Highway, Boisar, District – Palghar, India – 401501
- Mandatory or Special Controls per section 514 of the FD&C Act: No applicable mandatory performance standards or special controls exist for this device

The reason for this premarket notification is to provide notification of a new substantially equivalent device prospectively introduced into commercial distribution by Laxmi Dental Lab USA, Inc., subject to the review of this notification.

The device represented within this premarket notification is of substantial equivalence to comparable devices in commercial distribution.

The primary Laxmi Dental Lab USA, Inc., contact for this document is,
Mr. Kunal Merchant
Laxmi Dental Lab USA, Inc.
100 Hollister Rd
Teterboro, NJ 07608, United States

Respectfully submitted,

(b)(6)

Kunal Merchant, President

Section 3 - 510(K) Summary of Safety and Effectiveness

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	Biocompatibility 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) Animal | Human Testing 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.

Section 4 - Description of Device and Specifications

Section 4 - Device Description and Summary of Technological Characteristics

Technical Description

The 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 contains a series of doctor approved, customized processed, clear plastic removable aligners that gradually move the patient's teeth in small increments from their original misalignment to a more optimal, aligned and treated stated.

Laxmi Dental Exports Pvt Ltd. manufactures the customized aligners based on standard impressions sent to the company by the prescribing dentist or orthodontist. These are made after the clinician has assessed the patient's teeth, designed a treatment plan, and taken the impressions.

Laxmi Dental Exports Pvt Ltd. manufactures models from the impressions and then scans the models using standard validated software. The digital files are used to produce the aligners series using **(b)(4)** PET-G thermoplastic.

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.

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 Configuration

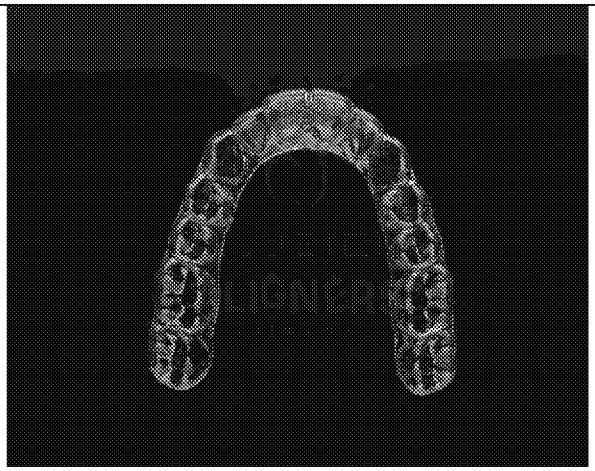
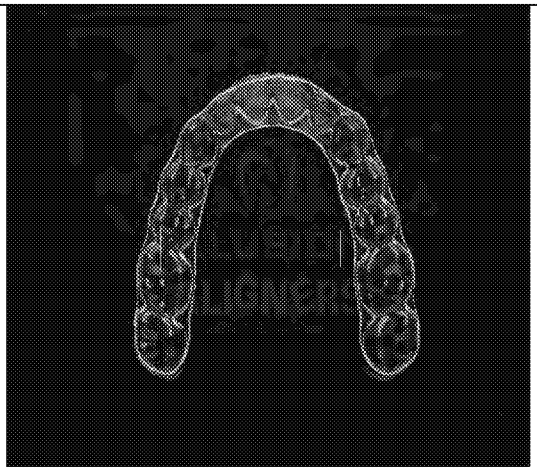
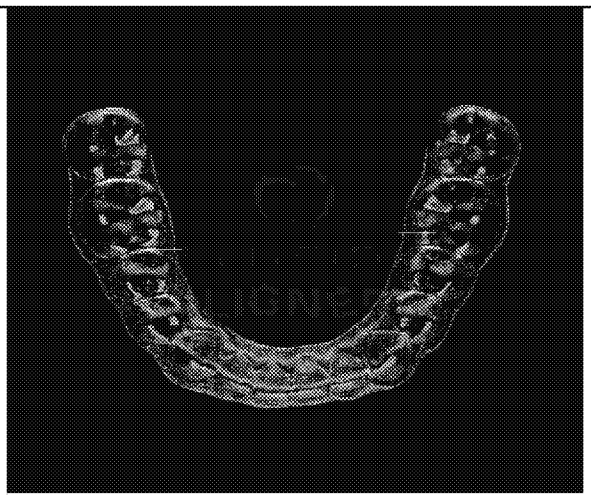
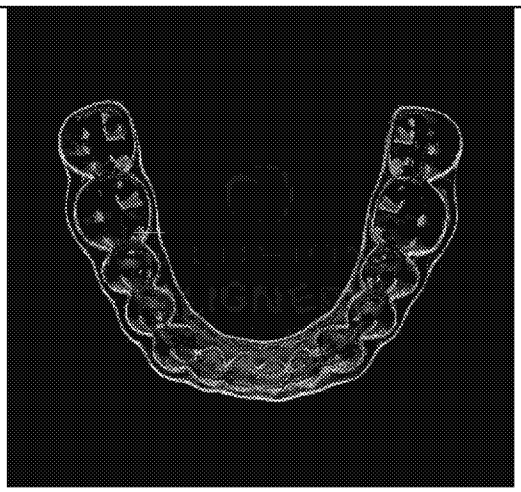
Illusion Aligners are intraoral thermoformed plastic aligners that are worn at least 22 hours per day and are designed to be used in a sequence, each aligner providing a gentle continuous force, to allow for the movement of teeth to the final desired position. The aligners are to be removed for eating and for cleaning. Illusion Aligners are fabricated using a **(b)(4)** step process. **(b)(4)** obtain the dimensions and details of the patient's baseline dentition. This is generally done using an oral scan data or a physical impression. This scanned data (digital CAD/CAM models or patient models) are imported into specialized dental software for treatment planning. **(b)(4)** **(b)(4)** Laxmi Dental Exports Pvt Ltd 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 molds needed for each treatment step to provide the surface around which the aligner is thermoformed. **(b)(4)** is the thermoforming of a plastic sheet material to each of the sequential treatment steps. This process is done using a standard thermoforming equipment and the appropriate material as outlined in this submission.

General configuration is represented in the following photographs. Each aligner produced is custom to the patient/client impression.

Configuration: **Illusion Aligners representation, typical**

Material: (b)(4) **Polyethylene terephthalate glycol (PETG)**

Date: 09.29.20

	Exterior View	Interior View
Maxillary (Upper) Tray		
Mandibular (Lower) Tray		

Material Specification

Laxmi Dental Exports Pvt Ltd. will manufacture the Illusion Aligners from material, (b)(4) Polyethylene terephthalate glycol (PETG) .Please see as follows the material specific sheet and MSDS.

(b)(4)

(b)(4) Physical Performance Specification Testing

(b)(4)

MSDS

(b)(4)

MATERIAL DATA SHEET
(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Manufacturing Flowchart

ILLUSION ALIGNERS PROCESS FLOW

(b)(4)

Study Report - Illusion Aligners Manufacturing Process Validation Data Collection and Analysis Date: 30/09/20

(b)(4)

(b)(4)

(b)(4)

(b)(4)

MANUFACTURING PROCESS VALIDATION STUDY

(Process Description and Raw Data)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

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(b)(4)

(b)(4)

Section 5 - Shelf Life

Section 5 - Shelf Life

The Illusion Aligners is a prescription device which is custom fabricated to the doctor's approved treatment plan/prescription and is intended for immediate use during typically 20 weeks of treatment using a series of sequential aligners. The device is not intended for retail sale and extended retail shelf storage. Storage conditions do not affect device safety or effectiveness of the aligner.

There is no FDA requirement for an medical device expiration date as an independent obligation. Instead an expiration date is an inherent part of the labeling requirement whenever a product has a critical characteristic that fundamentally changes over time.

Shelf-life dating solely for package integrity and sterility is not usually required by FDA for general medical devices.[a]

The Illusion Aligners is non-sterile, hence the non-need for a sterile barrier expiration date. Routine monitoring of the patient treatment progression and aligner fitment of sequential aligners by the prescribing physician and validation of the aligner dimensional conformance to the physician treatment plan. Both which provides that the device characteristics are monitored and do not fundamentally change over time (typically 20 weeks of treatment). There is no device componentry which has an independent expiration date

Therefore, a Illusion Aligners unit expiration date is not applied to the device labeling.

[a] FDA Quality System Regulation Labeling Requirements, content current as of: 08/31/2018 as cited at https://www.fda.gov/medical-devices/device-labeling/quality-system-regulation-labeling-requirements

Section 6 – Indications for Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

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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FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

Section 7 - Device Labeling and Advertising

Instruction for Use – Patient Draft

ILLUSION ALIGNERS INSTRUCTIONS FOR USE - PATIENT

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

RX Only – Single Patient Use Only – Disposable

Mode of Action: 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.

Cautions:

- May cause allergic skin reaction. Not likely to cause skin irritation. If allergic reaction occurs, immediately discontinue use and contact your physician-
- May not be appropriate to use on patients such as mixed dentition, teeth with short clinical crowns, arches with multiple missing teeth. Tooth shape and missing teeth may affect aligner fit.
- Illusion Aligners have certain limitations and are not considered the best solution for handling complex orthodontic cases such as severe deep overbites or severely rotated teeth. Functional indications, including consideration of indications related to function is limited to respiration, speech, abnormal habits, occlusal disturbances and forced bites, and the mandibular dysfunction syndrome.

Contraindications:

- Do not use on patients with active dental or periodontal disease.

Use

1. Each Aligner should be worn at least 22 hours per day for two weeks (14-15 days).
2. We suggest you wear the Aligner all the time except while eating, drinking and brushing your teeth.
3. Always remember to wash your hands thoroughly with soap and water before handling aligners.
4. We recommend when it is time for your next aligner, that you place new aligners at night before bed. This helps to alleviate the initial discomfort that you may experience.
5. After removal, rinse immediately with water, shake off excess and store your aligners in the protective case provided to you.

Insertion

1. You may insert either the upper or lower aligner first.
2. When inserting each aligner, gently push the aligners over your front teeth.
3. Then apply equal pressure using your fingertips, to the tops of your left and right molars (back teeth) until the aligner snaps into the place.
4. Gently push the aligner into place.
5. DO NOT BITE your aligners into position, this may damage the aligners.

Removal

1. To remove your aligners, use your fingers, starting on one side at the molars (back teeth) and slowly work your way around to the other side lifting gently.
2. NOTE: Use care in removing your aligners, DO NOT use any sharp object to remove the aligners.

Clean

1. Proper oral hygiene is a must. Aligners should be cleaned every day with a soft toothbrush and cold running water, morning and night.

2. During the day, rinse your mouth and aligners with water to remove any remaining food, after you eat.
3. No matter which option you choose, make sure you give your teeth and aligners a good brushing before you go to bed.

Avoid the following:

DO NOT use toothpaste/denture cleaners/mouthwash or any extreme cleansers on your aligners. It will make your aligners become cloudy and less clear.
Never expose your Aligner to heat to clean or sterilise; heat will distort the appliance and it will not fit correctly.

Custom laser marking

1. This guide explains how to read your aligner bags and aligners, to ensure you are wearing the correct ones.
2. To help avoid confusion, each aligner is marked with your unique case number, the stage number, followed by a "U" for upper and an "L" for lower arch.

Storage

1. It is vital to store your aligners in their case when not wearing them.
2. Please do not put your aligners in a tissue or pocket as they may be thrown out or break.
3. Keep out of reach of children and pets!
4. CAD/CAM 3D printed transition models are provided (patients are liable to keep them all till the final stage of the treatment).

Lost or damage

In the event that an aligner is lost or broken, you should immediately inform your doctor. Your doctor will probably tell you to start wearing your last set or next set of aligners immediately. He or she will possibly order you a new set of aligners to replace the ones you just lost, which should arrive in a few days.

Laxmi Dental Exports Pvt Ltd., Survey No. 201/1, Village Gundale, Boisar Chillar Highway, Boisar, District – Palghar, India – 401501

Part No.: Rev No.

Instruction for Use – Clinician Draft

ILLUSION ALIGNERS INSTRUCTIONS FOR USE – CLINICIAN

Description: A dental health professional (e.g. an orthodontist or a dentist) prescribes the Illusion Aligners 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 fills the work authorization form using a standard dental software used for tooth alignment. Illusion Aligners 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 are fabricated using a three-step process.
The first step is to obtain the dimensions and details of the patient's dentition. This is generally done using an oral scan data or a physical impression. This scanned data (digital CAD/CAM models or patient models) are 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 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 a 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.

Mode of Action: 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 progresses over time.

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.

RX Only - Single Patient Use Only – Disposable

Cautions:

- May cause allergic skin reaction. Not likely to cause skin irritation. If allergic reaction occurs, immediately discontinue use and contact your physician.
- May not be appropriate to use on patients such as mixed dentition, patients with active dental or periodontal disease, teeth with short clinical crowns, arches with multiple missing teeth. The tooth shape and missing teeth may affect aligner fit.
- Illusion Aligners have certain limitations and are not considered the best solution for handling complex orthodontic cases such as severe deep overbites or severely rotated teeth. Functional indications, including consideration of indications related to function is limited to respiration, speech, abnormal habits, occlusal disturbances and forced bites, and the mandibular dysfunction syndrome.

Contraindications:

- Do not use on patients with active dental or periodontal disease.

Unit Label - Draft

Description: Laxmi Illusion Dental Aligner

Upper 1 of XX
Lower 1 of XX

Company Name/Logo Here

Lot Number: **ABC123**

Expiration Date: **mm/dd/yyyy**

Patient Name: **XXXX XXXXX**

Patient I.D.: ######

Single Patient Use Only, Disposable

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

Rx only

Manufactured by:
Laxmi Dental Exports Pvt Ltd, Inc.
Survey No. 201/1, Village Gundale, Boisar Chillar Highway
Boisar , District – Palghar, India – 401501

GUDID Bar Code Here

GUDID Human Readable Text Here

Section 8 Biocompatibility Information

Section 8 - Biocompatibility

Illusion Aligners are classified in accordance with ISO 10993-1 as follows:

• Nature of Body Contact: Surface Device, Intact Skin

• Contact Permanent: C – Prolonged (>30days)

Material Biocompatibility – (b)(4) **Polyethylene terephthalate glycol (PETG),** (b)(4)

Line	Standard	Title	Report Reference	Date	Pass/Fail	Page No
1	ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro **cytotoxicity**	(b)(4)	04/25/19	(b)(4)	70
2	ISO 10993-10:2010	Biological Evaluation of Medical Devices-Tests for **Irritation** and Skin Sensitization		05/02/19		94
3	ISO 10993-10:2010	Biological Evaluation of Medical Devices-Tests for Irritation and **Skin Sensitization** (Guinea Pig Maximization Test)		05/29/19		122

1. ISO 10993-5 Cytotoxicity report

(b)(4)

(b)(4)

FINAL REPORT

(b)(4)

Test for *in vitro* Cytotoxicity: Elution Method of (b)(4) ALIGNER AND RETAINER (Batch No.: (b)(4) as per ISO 10993-5:2009(E).

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ISO 10993-10 Irritation Test

(b)(4)

(b)(4)

FINAL REPORT

(b)(4)

Skin Irritation Test in New Zealand White Rabbits of (b)(4) ALIGNER AND RETAINER (Batch No.: (b)(4) as per ISO 10993-10:2010 (E).

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FINAL REPORT

(b)(4)

Skin Sensitization Test in Guinea Pigs (Guinea Pig Maximization Test) of (b)(4) ALIGNER AND RETAINER (Batch No.: (b)(4) as per ISO 10993-10:2010 (E).

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Section 9 - Predicate Device Comparison Table

Section 9 - Predicate Device Comparison Table

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
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.	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 Material (Polyethylene terephthalate glycol)	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

(b)(4)

(b)(4)

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.

Section 10 – Predicate Labeling

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(b)(4)

Section 11 – Truth and Accuracy Statement

Section 12 – Truth and Accuracy Statement

Premarket Notification Truthful and Accurate Statement [As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as president of Laxmi Dental Exports Pvt Ltd. I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)

(Signature)

Sameer Merchant

(Typed Name)

(Date) 11.12.20

*(Premarket Notification [510(k)] Number)*For a new submission, leave the 510(k) number blank

Section 2 - Cover Letter

K211010

FDA/CDRH/DCC

APR 05 2021

RECEIVED

LAXMI DENTAL LAB USA INC.
100 Hollister Rd, Unit 1, Teterboro, NJ 07608 1.855.go.laxmi

Food and Drug Administration
Center for Devices and Radiological Health (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Subject: Premarket Notification Submission – 510(k) Traditional, Illusion Aligners

To whom it may concern;

Laxmi Dental Lab USA, Inc is submitting the enclosed Premarket Notification, 510(k) for Illusion Aligners, prepared and formatted in accordance with 21CFR807.

- Proprietary Trade Name: Illusions Aligners
- Common Name: Orthodontic Tray Aligner
- Condition: Non-Sterile
- Classification Name: aligner, sequential
- Establishment Registration Number: 3009432549
- Class: II
- Panel: Dental
- Code: NXC
- Regulation: 21CFR872.5470
- Predicate medical device: K173784, Smylio Invisible Clear Aligners
- Manufacturer: Laxmi Dental Exports Pvt Ltd., Survey No. 201/1, Village Gundale, Boisar Chillar Highway, Boisar, District – Palghar, India – 401501
- Mandatory or Special Controls per section 514 of the FD&C Act: No applicable mandatory performance standards or special controls exist for this device

The reason for this premarket notification is to provide notification of a new substantially equivalent device prospectively introduced into commercial distribution by Laxmi Dental Lab USA, Inc., subject to the review of this notification.

The device represented within this premarket notification is of substantial equivalence to comparable devices in commercial distribution.

The primary Laxmi Dental Lab USA, Inc., contact for this document is,
Mr. Kunal Merchant
Laxmi Dental Lab USA, Inc.
100 Hollister Rd
Teterboro, NJ 07608, United States

Respectfully submitted,

(b)(6)

Kunal Merchant, President

03-1

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.

U.S. FOOD & DRUG ADMINISTRATION

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 -S

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.

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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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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.

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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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)

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K211010

I. Cover Letter - 510(k) Third Party Review

Date: April 3rd, 2021

FDA – CDRH
Document Control Center – WO66-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: New 3rd Party Review Memo

A. **Purpose of Submission:** NEW DEVICE

B. **Name and Address of the 3P Review Organization**
Rafael Aguila, *Responsible Third-Party Official*
Accelerated Device Approval Services, LLC
6800 S.W. 40th Street, Ste. 403
Ludlum, FL 33155-3708
Tel.: 1-866-669-8370
E-Mail: support@510k-review.com

C. **Name and Address of the 510(k) Submitter**
Laxmi Dental Exports Pvt Ltd. - Survey No. 201/1, Village Gundale, Boisar Chillar Highway, Boisar, District – Palghar, INDIA – 401501

D. **Device Name**
Trade or Proprietary Name: Illusion Aligners
Common or Usual Names: Orthodontic Plastic Bracket — **Class:** II
Classification Regulation Number: 21 CFR 872.5470 — **Product Code:** NXC
FDA classification regulation name: Aligner, Sequential

E. **Recommendation:** (b)(4)

F. The date that the 510(k) submission was received by the Accredited Person was on November 13, 2020

We have enclosed the following materials:

II. Authorization Letter from the Applicant.
III. 510(k) Third Party Submission Certification.
IV. Conflict of Interest Declaration and Certification - Final Reviewer.
V. Conflict of Interest Declaration and Certification - Product Specialist.
VI. An acceptance review of the 510(k) submission based on objective criteria using the RTA checklist.
VII. 510(k) Third Party Review Memorandum.

Sincerely,

(b)(6)

Rafael Aguila, RAC
Responsible Third-Party Official