January 8, 2020

Royal Dental Lab
% Becky Chen
Registered Engineer
Feiying Drug & Medical Consulting Technical Service Group
B-3F-3005, Bldg.1, Southward Ruifeng Business Center, No.22 Guimiao Rd.,
Shenzhen, Guangdong, 518000 P.R.China

Re: K192767
Trade/Device Name: Clear Aligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: September 26, 2019
Received: September 30, 2019

Dear Becky Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K192767

Device Name
Clear Aligner

Indications for Use *(Describe)*
This device is indicated for use in the alignment of permanent teeth 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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K192767 - 510 (k) Summary

This "510(k) Summary" of 510(k) safety and effectiveness information is submitted in accordance with requirements of Title 21, CFR Section 807.92.

(1) Applicant information

510 (k) owner's name:	Royal Dental Lab
Address:	F/1, 2, 3, 5, 6, Building 2, No. 4 West Area, Shangxue Industry Park, Bantian, Longgang, Shenzhen, Guangdong, China
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Fax number:	+86-0755-89501749
Email:	fiona@china-dental.com
Date of summary prepared:	2019.09.26

(2) Reason for the submission

New device, there were no prior submissions for the device.

(3) Proprietary name of the device

Trade name/Model:	Clear Aligner
Common name	Aligner, sequential
Regulation name:	Orthodontic plastic bracket
Regulation number: Product code	21 CFR 872.5470 NXC
Review panel: Regulation class:	Dental Class II

(4) Primary Predicate

Sponsor	Smylio, Inc.
Device Name and Model	Smylio Invisible Clear Aligners
510(k) Number	K173784
Product Code	NXC
Regulation Number	21 CFR 872.5470
Regulation Class	II

(5) Reference device

This reference device - 3Shape Ortho System ™ is the software which used for the manufacturing

process of Clear Aligner.

Sponsor	3Shape A/S
Device Name and Model	3Shape Ortho System ™ Software
510(k) Number	K152086
Product Code	PNN, LLZ
Regulation Number	21 CFR 872.5470
Regulation Class	II

(6) Description/ Design of device

The Clear Aligner is intraoral thermoformed plastic aligner that worn 20 to 22 hours per day and is 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 aligner is to be removed for eating and for cleaning.

Clear Aligner is fabricated using a three-step process.

The first step 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 by a dental health professional (e.g. clinician). 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, the doctor 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. A 3D printer is used to create the molds 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 outlined in this submission.

Specialized orthodontic CAD/CAM software will be used to develop the treatment plans and to produce standard 3D printer files that will facilitate the manufacturing of each sequential aligner in the treatment plan. The software application used for the manufacturing validation is this submission is the 3Shape Ortho System ™ Software which have 510(k) (K152086).

(7) Intended use/ Indications for use

This device is indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.

(8) Materials

Component of Device Requiring	Material of Component	Body Contact Category (ISO 10993-1)	Contact Duration (ISO 10993-1)

Biocompatibility			
plastic sheet material	Co-polyester or Co-polymer	Surface-contacting device: Mucosal membrane	< 24 hours

The body-contacting material (plastic sheet material) used in Clear Aligner has passed biocompatibility tests. Details can be seen in "Biocompatibility Discussion".

(9) Technological characteristics and substantial equivalence

Item	Subject device	Predicate device	Remark
Trade name	Clear Aligner	Smylio Invisible Clear Aligners	/
510 (k) number	K192767	K173784	/
Regulation number	21 CFR 872.5470	21 CFR 872.5470	Same
Regulation name	Orthodontic plastic bracket	Orthodontic plastic bracket	Same
Product code	NXC	NXC	Same
Class	II	II	Same
Indications for use/ Intended use	This device is indicated for use in the alignment of permanent teeth 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.	Same
Prescription or OTC	Prescription Use	Prescription Use	Same
Materials	Co-polyester or Co-polymer	Co-polyester or Co-polymer	Same
Mode of Action	Continuous gentle force applied to teeth to achieve movement.	Continuous gentle force applied to teeth to achieve movement.	Same
Manufacturing method	Thermoforming	Thermoforming	Same
Device description	Sequential thermoformed plastic aligner	Sequential thermoformed plastic aligners	Same
Patient Removable?	Yes	Yes	Same
Duration of Use	20-22 hours per day	20-22 hours per day	Same
Biocompatibility	Passed the tests as per ISO 10993-5 and ISO 10993-10 (Cytotoxicity, sensitization, irritation)	Passed the tests as per ISO 10993-5 and ISO 10993-10 (Cytotoxicity, sensitization, irritation)	Same
Sterility	Non-sterile	Non-sterile	Same
Anatomical site	Used by dentist or orthodontist on teeth for dental patients.	Used by dentist or orthodontist on teeth for dental patients.	Same

Conclusion:

The only difference between the subject and predicate devices are the manufacturer and distributor of the device. Based on the above analysis, the Clear Aligner is substantial equivalent to the predicate device.

(10) Non-clinical studies and tests performed

Non-clinical testings have been conducted to verify that the Clear Aligner meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device.

Manufacturing Validation

A manufacturing validation was performed to demonstrate the manufacturing process for Clear Aligner. Three critical aspects of the manufacturing process were assessed: digital dentition models from treatment planning, 3D printed molds, and the final thermoformed aligner.

An independent 3rd party software and digital calipers were used to perform point-to-point and critical displacement measurement.

All translational measurements were within 0.3mm of the target input value and all rotational measurements were within 3 degrees of the target input value, the predefined tolerance of the manufacturing process. There were no statistical differences in the difference in the intended and measured values observed from any of the groups. This test has met the pre-established acceptance criteria.

Biocompatibility

A biocompatibility discussion was conducted. The Clear Aligner uses the Zendura plastic sheet material and this material has been tested and shown to be compliant with the following standards:

- ISO 7450: 2008, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
- ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5, Biological Evaluation Of Medical Devices -- Part 5: Tests For InVitro Cytotoxicity
- ISO 10993-10, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization

(11) Clinical studies and tests performed

Clinical studies and tests were not conducted.

(12) Conclusion

Based on the above analysis and tests performed, it can be concluded that the performance and function of Clear Aligner are normal, and it is Substantially Equivalent (SE) to the predicate device