September 22, 2021

Smylio, Inc
% Breanne Butler
Regulatory Affairs Consultant
Prime Path Medtech
1321 Upland Dr. Suite 6792
Houston, Texas 77043

Re: K212660
Trade/Device Name: Smylio Invisible Clear Aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: August 19, 2021
Received: August 23, 2021

Dear Breanne Butler:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K212660

Device Name
Smylio Invisible Clear Aligners

Indications for Use *(Describe)*
The Smylio Invisible Clear Aligners are indicated for the alignment of teeth during orthodontic treatment of 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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Section 5. 510(k) Summary

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information for this special 510(k) in accordance with the requirements of 21 CFR 807.92.

Submitter: Smylio, Inc.
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Date Prepared: August 2nd, 2021

Proprietary Name: Smylio Invisible Clear Aligners

Common Name: Orthodontic plastic bracket.

Product Code: NXC – Orthodontic plastic bracket.

Device Classification: Class II, 21 CFR 872.5470

Primary Predicate Device: Spark Clear Aligner System (K203737)

Reference Predicates: Invisalign System (K143630)
Smylio Invisible Clear Aligners (K173784)

Device Description:

The Smylio Invisible Clear Aligners are thermoformed plastic aligners designed to be worn in sequence to facilitate the movement to the teeth to the final desired position. The sequential aligners introduce incremental movements that move teeth by way of gentle continuous force. The aligners are to be worn 20 to 22 hours a day and are to be removed for eating and for cleaning.

Smylio Invisible Clear Aligners are designed from digital scans of a patient's dentition submitted by a dental health professional (e.g. dentist or orthodontist). Using the scan, sequential dental models are designed and approved by the treating physician prior to manufacturing.

Once the treatment plan is reviewed and approved by a dental health professional, each 3D model from the treatment plan is manufactured. The aligner trays are then manufactured by thermoforming a dental thermoplastic sheet over each model. The aligner trays are then delivered to the patient . The patients'

dental health professional then monitors their treatment from the placement of the first aligner to the delivery of the final aligner.

Indications for Use:

The Smylio Invisible Clear Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion.

Comparison to Predicate Devices:

Smylio Invisible Clear Aligners are functionally equivalent to the following predicate device: Spark Clear Aligner System (K203737, cleared March 22, 2021) and to the previously cleared reference device, Smylio Invisible Clear Aligners (K173784). The following table demonstrates the functional specifications of Smylio Invisible Clear Aligners are substantially equivalent to the predicate devices.

Device Comparison Table

Specification	**Subject Device:** Smylio Invisible Clear Aligners	**Predicate Device:** Spark Clear Aligner System (K203737)	**Reference Device:** Smylio Invisible Clear Aligners (K173784)	**Comparison Result**
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	21 CFR 872.5470	Same
Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Same
Product Code	NXC	NXC	NXC	Same
Classification	Class II	Class II	Class II	Same
OTC or Rx	Rx	Rx	Rx	Same
Material	Thermoplastic polyurethane-polyester composite resin	Thermoplastic polyurethane-polyester composite resin	Co-polyester or co-polymer	Same as predicate
Material Properties	Acceptable material properties established for use as an aligner.	Acceptable materials properties established for use as an aligner.	Acceptable materials properties established for use as an aligner.	Same
Material Testing	ASTM D790-10: Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials.	ASTM D790-10: Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials.	ASTM D790-10: Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials.	Same
Biocompatible	Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system).	Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system).	Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system).	Same
Sterile	Non-sterile	Non-sterile	Non-sterile	Same

Specification	Subject Device: Smylio Invisible Clear Aligners	Predicate Device: Spark Clear Aligner System (K203737)	Reference Device: Smylio Invisible Clear Aligners (K173784)	Comparison Result
Device Description	Sequential thermoformed plastic aligners	Sequential thermoformed plastic aligners	Sequential thermoformed plastic aligners	Same
Patient Removable?	Yes	Yes	Yes	Same
Indication for Use	The Smylio Invisible Clear Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion.	The Spark™ Clear Aligner System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.	The Smylio Invisible Clear Aligners is indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.	Same as predicate.
Intended Use	Orthodontic tooth movement	Orthodontic tooth movement	Orthodontic tooth movement	Same
Mode of Action	Continuous gentle force applied to teeth following the prescribed and approved treatment plan to achieve orthodontic movement	Continuous gentle force applied to teeth following the prescribed and approved treatment plan to achieve orthodontic movement	Continuous gentle force applied to teeth following the prescribed and approved treatment plan to achieve orthodontic movement	Same

Comparison of Indications for Use to Predicate Devices and Previously Cleared Devices:
The indications for use of the Smylio Invisible Clear Aligners in this submission is the same as the Spark Clear Aligner System (K203737) as they are both indicated for use in the alignment of teeth through orthodontic treatment of malocclusion. The differences between the indications for use of the subject device and the previously cleared device (K173784) do not raise questions of substantial equivalence. The aligners guide teeth to their final position by way of continuous gentle forces. Thus, the Smylio Invisible Clear Aligners can be considered substantially equivalent to its predicate device.

The difference between the Smylio Invisible Clear Aligners in this submission (Subject Device) and the Reference Device, Smylio Clear Aligners (K173784) is the material. The material of the subject device is the same as the predicate device.

Comparison of Technological Characteristics to Predicate Devices:
Based on the above comparison, the design, construction, and performance characteristics of the Smylio Invisible Clear Aligners is the same as the predicate and similar to the reference device. Thus, the Smylio Invisible Clear Aligners can be considered substantially equivalent to its predicate device.

Non-clinical performance testing:
The use of thermoplastic materials for sequential aligners intended to treat malocclusions has been well documented in scientific literature regarding incremental tooth moving forces. However, durability

testing was conducted on the aligners. Real world use was simulated to ensure that the aligner material and manufacturing process produced aligners that were suitable for their prescribed period of use.

An internal manufacturing validation was performed to test the manufacturing process for Smylio Invisible Clear Aligners. The robustness of the process was demonstrated from 3D printing through thermoforming.

The thermoplastic material used for Smylio Invisible Clear Aligners has passed the required testing for material characterization. Material testing was conducted on the aligner material according to ASTM D790-10: Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials. Biocompatibility testing for the aligner material, the only patient contacting material, was conducted in accordance with International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". Additional cytotoxicity testing according to ISO 10993-5:2009 was performed on final manufactured Smylio Invisible Clear Aligners.

Clinical performance testing:
Clinical performance testing was not conducted for this 510(k) Notification. Clinical performance testing was not needed to establish substantial equivalence to the predicate device or to characterize performance. The above-mentioned non-clinical test data characterizes all performance aspects of the device based on well-established scientific and engineering principles. .

Conclusion:
Based on similarities in indications for use, technological characteristics, non-clinical performance testing, Smylio Invisible Clear Aligners are substantially equivalent to the Spark Aligner System and the previously cleared Smylio Invisible Clear Aligners (K173784).