April 5, 2023

Smylio Inc.
℅ Jennifer Day
Regulatory Affairs Consultant
Prime Path Medtech
1321 Upland Dr. Suite 6792
Houston, Texas 77043

Re: K221537
Trade/Device Name: Nightwear Aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: May 26, 2022
Received: May 27, 2022

Dear Jennifer Day:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221537

Device Name
Nightwear Aligners

Indications for Use *(Describe)*
Nightwear Aligners are indicated for the alignment of permanent 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Attachment A: 510(k) Summary

510(k) SUMMARY

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

Submitter: Smylio Inc.
48890 Milmont Dr
Suite 101D
Fremont CA, 94538

Company Contact Person: Ren Menon, CEO
Phone: 510-868-2184
Email: rmenon@orthofx.com

Submission Correspondent: Jennifer Day, Regulatory Affairs Consultant
Breanne Butler, PhD
Company: Prime Path Medtech Inc.
Address: 1321 Upland Dr, Ste 6792 Houston, TX 77043
Phone: 860-810-5594
Email: jday@primepathmedtech.com

Date Prepared: May 26, 2022

Proprietary Name: Smylio Nightwear Aligners

Common Name: Orthodontic plastic bracket.

Product Code: NXC – Orthodontic plastic bracket.

Device Classification: Class II, 21 CFR 872.5470

Primary Predicate Device: iSMILE Aligners (K200908)

Reference Predicates: Smylio Invisible Clear Aligners (K212660)
Smylio Invisible Clear Aligners (K173784)

Device Description:

The Smylio Nightwear 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 at least 9 to 12 hours a day and are to be removed for eating and for cleaning.

Smylio Nightwear 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 aligners are shipped to the treating clinician's office where they are then distributed to the patient in sequential stages. 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:

Nightwear Aligners are indicated for the alignment of permanent teeth during orthodontic treatment of malocclusion.

Comparison to Predicate Devices:

Smylio Nightwear Aligners are functionally equivalent to the following predicate device: iSMILE Aligners (K200908). The following table demonstrates the functional specifications of Smylio Nightwear Aligners are substantially equivalent to the predicate devices.

Table 1. Predicate Device Comparison Table

Specification	**Subject Device:** Smylio Nightwear Aligners	**Predicate Device:** iSMILE Aligners (K200908)	**Comparison Result**
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	Same
Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Same
Product Code	NXC	NXC	Same
Classification	Class II	Class II	Same

Specification	**Subject Device:** Smylio Nightwear Aligners	**Predicate Device:** iSMILE Aligners (K200908)	**Comparison Result**
OTC or Rx	Rx	Rx	Same
Material	Thermoplastic Polymer	Thermoplastic Polymer	Same
Material Properties	Demonstrates sufficient tensile strength, elasticity, ductility, chemical resistance, and clarity for use as a clear tray aligner.	Demonstrates sufficient tensile strength, elasticity, ductility, chemical resistance, and clarity for use as a clear tray aligner.	Same
Biocompatible	Yes	Yes	Same

Specification	**Subject Device:** Smylio Nightwear Aligners	**Predicate Device:** iSMILE Aligners (K200908)	**Comparison Result**
Device Description	Nightwear Aligners are a sequence of transparent aligners created from a digital orthodontic treatment plan. The Nightwear Aligners are fabricated of a transparent thermoformed polyurethane plastic. Each aligner delivers a unique combination of minor forces to create the planned tooth movement. The digital orthodontic treatment plan is created by a dental health professional. The Nightwear Aligners incorporate the use of attachments to create spaces and force points in order to cause minor tooth movement. These force points are located in specific areas and positioned in such a way that they provide a continuous force which slowly dissipates over time on the tooth to be moved for as long as the aligner is worn.	The iSMILE is a sequence of transparent aligners created from a digital orthodontic treatment plan. The iSMILE aligner is fabricated of a transparent thermoformed polyurethane plastic. Each aligner delivers a unique combination of minor forces to create the planned tooth movement. The digital orthodontic treatment plan is created by a dental health professional. The iSMILE Aligner incorporates the use of attachments to create spaces and force points in order to cause minor tooth movement. These force points are located in specific areas and positioned in such a way that they provide a continuous force which slowly dissipates over time on the tooth to be moved for as long as the aligner is worn.	Same
Anatomy Location	Mouth; mucosal	Mouth; mucosal	Same
Size	Patient Specific	Patient Specific	Same

Specification	**Subject Device:** Smylio Nightwear Aligners	**Predicate Device:** iSMILE Aligners (K200908)	**Comparison Result**
Manufacturing Method	Thermoforming	Thermoforming	Same
Patient Removable?	Yes	Yes	Same
Indication for Use	Nightwear Aligners are indicated for the alignment of permanent teeth during orthodontic treatment of malocclusion.	iSMILE is indicated for the alignment of teeth during orthodontic treatment of malocclusion.	Same
Mode of Action	Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription	Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription	Same

Comparison of Indications for Use to Predicate Devices:

The indications for use of the Smylio Nightwear Aligners are the same as the iSMILE Aligners (K200908) as they are both indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion. The aligners guide teeth to their final position by way of continuous gentle forces. Thus, the Smylio Nightwear Aligners can be considered substantially equivalent to its predicate device.

Comparison of Technological Characteristics to Predicate Devices:

Based on the above comparison, the design, construction, and performance characteristics of the Smylio Nightwear Aligners is similar to that of the iSMILE Aligners (K200908). Thus, the Smylio Nightwear 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 Smylio Nightwear 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.

Material property testing was performed to investigate elongation, tensile and flexural properties of the material in accordance with ASTM D638 and ASTM D790.

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

The thermoplastic material used for Smylio Nightwear Aligners is broadly used in many aligners. Biocompatibility testing for the aligner material, the only patient contacting material, was in accordance with the International Standard "Biological evaluation of medical devices" ISO 10993-1, ISO 10993-5:2009, ISO 10993-10:2010, ISO 10993-10:2010, and ISO 10993-11:2017.

Clinical performance testing:

Clinical performance testing was conducted on 20 patients for the Smylio Nightwear Aligners under an FDA cleared IDE application (G200298). The study results demonstrated that tooth alignment may occur for patients with at least 9 to 12 hours of wear time per day for one week prior to moving to the next aligner for patients with mild malocclusions as determined by the treating dentist.

Conclusion:

Based on similarities in indications for use, technological characteristics, non-clinical performance testing, and clinical performance testing, Smylio Nightwear Aligners are substantially equivalent to the iSMILE Aligners (K200908).