December 16, 2019

Sun Dental Laboratories, LLC
℅ Paul Dryden
President
Sun Dental Laboratories, LLC / ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K190394
Trade/Device Name: SunClear Aligner system
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: November 13, 2019
Received: November 14, 2019

Dear Paul Dryden:

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 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)*
K190394

Device Name
Sun Clear Aligner system

Indications for Use *(Describe)*

The SunClear Aligner system is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). SunClear Aligners positions teeth by way of continuous gentle force.

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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Date Prepared: 13-Dec-2019

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Proprietary or Trade Name: SunClear Aligner system

Common/Usual Name: Sequential aligner and software

Classification Name:
21CFR 872.5470
NXC – Aligner, Sequential
Class II

Predicate Device: K172765 - Smart Moves Complete

Reference Device: K150702 - eXceed Computerized Precision Bracket Placement Solution

Device Description:
Orthodontic treatment is conventionally performed using brackets and arch wires. A bracket is bonded to each tooth and a wire is inserted with the goal of moving each tooth to a desired final treatment position. An alternative to traditional bracket treatment has been in existence for the past 20 years. This alternative treatment uses clear plastic aligners to gradually move the teeth. The aligners are designed in a series of incremental stages. A patient wears each aligner stage for a period of two weeks to accomplish the programmed tooth movement. Once tooth movement has been accomplished for a given stage the current aligner is removed and the next aligner in the sequence is worn. This method of orthodontic treatment is popular with patients because it provides a virtually invisible appliance and avoids the appearance of braces on the teeth.

Indications for use:
SunClear Aligner system is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). SunClear Aligner positions teeth by way of continuous gentle force.

Patient Population:
Patients needing treatment of tooth malocclusion

Environments of use:
Home

The following table presents the comparison to support substantial equivalence.

The table below compares the key features of the proposed SunClear Aligner system with the identified predicate – K172765 – Smart Moves Complete and the reference K150702 - eXceed Computerized Precision Bracket Placement Solution and demonstrates that this proposed device can be found substantially equivalent.

Indications for Use – The Indications for Use are similar to predicate – K172765 – Smart Moves Complete. There is a difference between the proposed SunClear Aligner system and the reference K150702 – eXceed Computerized Precision Bracket Placement Solution, however, the software utilized in this submission is identical to what was cleared under K150702 and K172765.
Discussion – The Indications for Use are similar to predicate – K172765 – Smart Moves Complete.

Technology and construction – The technology and construction are similar to predicate – K172765 – Smart Moves Complete. There is a difference between the proposed SunClear Aligner system and the reference K150702 – eXceed Computerized Precision Bracket Placement Solution, in that K150702 is for brackets.
Discussion – The software is identical, and the aligners are manufactured the same as the predicate including the identical materials.

Environment of Use – The environments of use are similar to predicate - K172765 – Smart Moves Complete and the reference K150702 - eXceed Computerized Precision Bracket Placement Solution.
Discussion – The environment is similar to predicate and reference, namely – home use.

Patient Population – The patient population is similar to predicate K172765 – Smart Moves Complete and the reference K150702 - eXceed Computerized Precision Bracket Placement Solution **Discussion –** The patient population is similar to the predicate – K172765 – Smart Moves Complete.

Workflow – The patient actively interacts with the dentist / orthodontist. Interactions include the patient visits a dental office; Dentist/orthodontist completes a comprehensive exam, takes x-rays and clears patient for orthodontic treatment; Dentist/orthodontist takes dental impressions or scans of patient and completes diagnostic records and sends to the lab who in turn fabricates models, thermoforms aligners, and sends aligners to the dentist to confirm patient fit.

Non-Clinical Testing Summary –
Biocompatibility - No testing was performed as the material of the aligners is identical to the K062828 – Dentsply International – Aligner materials which has similar intended use and patient contact.

Bench testing - SunClear Aligners are made of similar aligner material as the predicate. The identified aligner material has been cleared under K06282 for the intended use. We have performed flexural strength of the subject device and predicate materials.

Substantial Equivalence Conclusion -
The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.

Device Comparison	**SunClear Aligner system**	**Predicate K172765 – Smart Moves Complete**	**Reference K150702 - eXceed Computerized Precision Bracket Placement Solution**
Model	SunClear Aligner system	Smart Moves Complete	eXceed Software
Indications for Use	SunClear Aligner system is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). SunClear Aligners positions teeth by way of continuous gentle force.	Smart Moves Complete is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). Smart Moves Complete positions teeth by way of continuous gentle force.	eXceed Computerized Precision Bracket Placement Solution is a software system intended for use as an aid in orthodontic treatment planning to correct Malocclusions in Orthodontic Patients. For use by dental professionals trained in orthodontic treatment, including radiographic analyses and treatment planning. eXceed Computerized Precision Bracket Placement Solution is intended for use with commercially available brackets currently used in standard orthodontic treatment. The end product is an indirect bonding tray for use by the Dental professional to place multiple brackets at the same time.
Target Population	Patients needing treatment of tooth malocclusion	Patients needing treatment of tooth malocclusion	Patients needing treatment of tooth malocclusion
Environment of Use	Home	Home	Home
OTC or Rx	Rx	Rx	Rx
Design	Single Patient, multi-use	Single Patient, multi-use	Single Patient, multi-use

Device Comparison	**SunClear Aligner system**	**Predicate K172765 – Smart Moves Complete**	**Reference K150702 - eXceed Computerized Precision Bracket Placement Solution**
Device Description	SunClear Aligners consists of a series of doctor-prescribed, thin, clear plastic removable orthodontic appliances (aligners) and proprietary 3-D software. The aligners gently move the patient's teeth in small increments from their original state to a more optimal, treated state. SunClear Aligners are intended as an alternative to conventional bracket technology and fixed appliances for the treatment of patients with malocclusion. The proprietary software generates the final image of a treated state and then interpolates a series of images that represent the intermediate teeth states. The dental practitioner then reviews these images to depict, edit, view, monitor, and approve an orthodontic treatment plan.	Smart Moves Complete consists of a series of doctor-prescribed, thin, clear plastic removable orthodontic appliances (aligners) and proprietary 3-D software. The aligners gently move the patient's teeth in small increments from their original state to a more optimal, treated state. Smart Moves Complete is intended as an alternative to conventional bracket technology and fixed appliances for the treatment of patients with malocclusion. The proprietary software generates the final image of a treated state and then interpolates a series of images that represent the intermediate teeth states. The dental practitioner then reviews these images to depict, edit, view, monitor, and approve an orthodontic treatment plan.	Using the images provided by the Dental Professional, the software creates a 3D model and identifies the ideal placement of the brackets. The file is sent to the Dental Professional for review and approval. The Dental Professional may adjust the final position of the bracket if desired. A 3D model is printed, and the brackets are placed on the model in the prescribed location, approved by the Orthodontist. An indirect bonding tray is fabricated with the brackets in place. The tray and brackets are sent to the Dental professional. The Dental Professional places the indirect tray using their chosen commercially available bracket adhesive
Technology	eXceed Software	eXceed Software (referred to as SmartMoves)	eXceed Software
	Using the images provided by the Dental Professional, the software creates a 3D model and identifies the ideal placement of the aligners.	Using the images provided by the Dental Professional, the software creates a 3D model and identifies the ideal placement of the aligners.	Using the images provided by the Dental Professional, the software creates a 3D model and identifies the ideal placement of the brackets.
Workflow	- Patient visits a dental office - Dentist/orthodontist completes a comprehensive exam, takes x-rays and clears patient for orthodontic treatment - Dentist/orthodontist takes dental impressions or scans of patient and completes diagnostic records and sends to the lab. Lab fabricates models, thermoforms aligners, and sends back to dentist to confirm patient fit.	Not known	Active patient clinician interaction throughout the treatment period

Device Comparison	**SunClear Aligner system**	**Predicate** **K172765 – Smart Moves Complete**	**Reference** **K150702 - eXceed Computerized Precision Bracket Placement Solution**
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.	N/A
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 aligner 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 aligner tray	N/A
Biocompatibility / Materials	K062828 Dentsply International Aligner Material	Great Lakes Splint Biocryl	N/A
Performance testing	Strength testing	Strength testing	N/A