February 24, 2020

3D Smile USA, Inc
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K200214
Trade/Device Name: 3D Predict
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: January 24, 2020
Received: January 28, 2020

Dear Prithul Bom:

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 Srivinas ‘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

510(k) Summary
3D Smile USA, Inc
3D Smile Predict
12/24/2019

5.1 ADMINISTRATIVE INFORMATION

Manufacturer Name	3D Smile USA, Inc 3675 Market Street Suite #200 Philadelphia, PA 19104 USA Telephone: +1 (920) 332 4344 Fax: n/a
Official Contact	Marina Domracheva, CEO
Email:	marina.domracheva@3d-smile.com

5.2 DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	3D Smile Predict
Common Name:	Aligners, sequential
Classification Name:	Orthodontic Plastic Bracket
Classification Regulations:	21 CFR 872.5470
Device Class:	Class II
Product Code:	NXC
Review Panel:	Dental Products Panel
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

5.3 PREDICATE DEVICE INFORMATION

The devices within this submission are substantially equivalent in indications, intended use and design principles to the following predicate and reference devices:

510(k)	Predicate Device Name	Company Name
K191990	OSW Aligner System	OSW Manufacturing, LLC

5.4 DEVICE DESCRIPTION

The 3D Smile Predict aligner system is a series of prescription-only clear plastic removable aligners intended to incrementally move a patient's teeth from an initial state to a different end state using a software-generated sequence of intermediate states. 3D Smile Predict Aligners sequentially reposition teeth by way of continuous gentle force.

A digital or traditional mold impression of the patient's teeth is provided by a dental health professional (e.g. orthodontist or dentist). From the digital data created of the patient's teeth, specialized orthodontic CAD/CAM software is used to develop treatment plans. Using the software, dental technicians design a series of intermediate models corresponding to each stage of treatment, gradually realigning the patient's teeth according to the dental health professional's prescription.

The prescribing doctor reviews and approves the model scheme and treatment plan before the molds/models are produced.

Once approved, the specialized orthodontic software is used to generate standard format 3D files which are used to physically produce each model/mold in the treatment plan for aligner fabrication. 3D Smile USA, Inc produces the aligner trays by thermoforming a plastic sheet over each model in the treatment plan. The aligner trays are sent to the dental health professional who then delivers them to the patient, confirming fit and design of the first stage of treatment. Additional trays are used sequentially by the patient to gradually move the teeth to the desired position. The dental health professional monitors treatment from the moment the first aligner is delivered to when the final aligner is finished and treatment complete. The aligners are held in place by pressure and can be removed by the patient at any time.

The technology is identical to that used by the Predicate device, OSW Aligner System (K191990) and a number of other sequential aligner systems currently being legally marketed.

5.5 INDICATIONS FOR USE

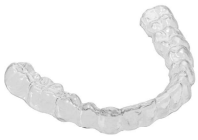
3D Smile Predict aligners are indicated for the alignment of teeth in patients with permanent dentition (i.e. all second molars) during orthodontic treatment of malocclusion.

5.6 EQUIVALENCE TO MARKETED DEVICE

Overall, the Subject device is substantially equivalent to the Predicate device with respect to Indications for Use and technological principles. The Comparison table below compares parameters and characteristics of the Subject device and Predicate/reference devices.

Predicate Device Comparison Table

Parameter	**Subject Device** 3D Smile Predict 3D Smile USA, Inc	**Predicate Device** OSW Aligner System OSW Manufacturing, LLC K180241
Regulation #	21 CFR 872.5470	21 CFR 872.5470
Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket
Product Code	NXC	NXC
Classification	Class II	Class II
Indications for Use	3D Smile Predict aligners are indicated for the alignment of teeth in patients with permanent dentition (i.e. all second molars) during orthodontic treatment of malocclusion.	OSW Aligner System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.
Mode of action	Orthodontic movement occurs through continuous gentle forces applied to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Orthodontic movement occurs through continuous gentle forces applied to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.
Method of use	Each appliance is worn by the patient as determined by the dental practitioner, generally 2 weeks prior to being replaced by the next aligner in sequence.	Each appliance is worn by the patient as determined by the dental practitioner, generally 2 weeks prior to being replaced by the next aligner in sequence.
3D Software Description	The 3D Smile Predict 3-D Software uses a scan of a PVS impression, physical or a digital scan (which represents an untreated state) to generate the image of a final, provisional treated state and then interprets a series of images that represent intermediate teeth states. The dental practitioner then reviews these images and has the option to reject or request modifications to the set-up prior to approving it for aligner fabrication. Once the dental practitioner approves the treatment plan, the software converts the files to produce the series of custom-made aligners.	The OSW Manufacturing 3-D Software uses a scan of a PVS impression or a digital scan (which represents an untreated state) to generate the image of a final, provisional treated state and then interprets a series of images that represent intermediate teeth states. The dental practitioner then reviews these images and has the option to reject or request modifications to the set-up prior to approving it for aligner fabrication. Once the dental practitioner approves the treatment plan, the software converts the files to produce the series of custom-made aligners.

Parameter	Subject Device 3D Smile Predict 3D Smile USA, Inc	Predicate Device OSW Aligner System OSW Manufacturing, LLC K180241
Function of the 3D software	The 3D Smile 3-D Software performs the following operations: • Produce 3D-model file of the patient's dentition from a digital scan. • Generates a treatment plan (i.e. 3-D models that represent the treatment plan) called a 3D plan based on the prescribing doctor's instructions. The treating dental practitioner reviews these images using 3D Smile software and has the option to reject or request modifications to the set-up prior to approval.	OSW Aligner System 3-D software performs the following operations: • Produce 3D-model file of the PVS impression or digital scan. • Identifies the individual teeth that will require treatment (i.e. repositioning). • Creates a treatment plan (i.e. 3-D models that represent the treatment plan). The treating dental practitioner reviews these images using OSWDP software and has the option to reject or request modifications to the set-up prior to approval.
Material	Thermoplastic	0.03" thick, thermoformed polyurethane
Appliance Application	Removable	Removable
Design		
Biocompatible	Yes	Yes
OTC or Rx	Rx	Rx
Sterile	Non-sterile	Non-sterile

The wording of the Indications for Use of the Subject device is slightly different than that of the Predicate device. At this time, the Subject device is indicated for patients with permanent dentition. This does not change the intended use of both Subject and Predicate devices to be used in the alignment of teeth during orthodontic treatment of malocclusion.

5.7 TECHNOLOGICAL CHARACTERISTICS

Orthodontic tooth movement occurs through forces applied to the teeth by the appliance as each tooth follows the predetermined displacement based on a dental health professional's prescription. The Subject device mode of action and method of use are identical to the Predicate device and supports a determination of substantial equivalence.

Even if the specific features or process of the Software used in treatment planning differs, the use of Software in treatment planning supports a determination of substantial equivalence. Most importantly, both verified and validated software programs rely on the prescribing doctor's approval of the treatment plan. The Subject and Predicate devices are both fabricated of a non-sterile, biocompatible thermoplastic material which supports a determination of substantial equivalence.

5.8 PERFORMANCE DATA

Due to the difficulty in evaluating this type of dental device in a laboratory environment, no direct performance bench testing of the aligners was performed. The use of thermoplastic materials for sequential aligners intended to treat malocclusions have been well documented in scientific literature regarding incremental tooth moving forces.

A manufacturing validation was performed to demonstrate the dimensional accuracy of the manufacturing process for 3D Smile Predict Aligners. Three critical aspects of the manufacturing process were assessed for accuracy: 3D printed molds, thermoformed aligner adaptation to the mold, thermoformed aligner to the software output.

Inspection software was used to perform point-to-point and critical displacement measurements.

All measurements were within the acceptance criteria. These test have met the pre-established acceptance criteria to demonstrate dimensional accuracy.

An aligner fit validation was performed to confirm fit of aligners on the patient.

5.9 CLINICAL TESTING

The performance of sequential aligners in the clinical environment has been well established since the first such devices were cleared by the FDA in 1998 under product code NXC. Therefore, there no clinical testing is required to support 3D Smile Predict Aligners, as the Indications for Use is equivalent to the Predicate device, which also was not subject to clinical testing. No clinical data is included in this submission.

5.10 BIOLOGICAL TESTING

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". The results of the tests satisfy the requirements of the study protocols and comply with ISO 10993-1 for the intended use.

The following biological tests were performed:

Biological Endpoint	Relevant Standard
Cytotoxicity	ISO 10993-5:2009
Sensitization	ISO 10993-10:2010
Irritation	ISO 10993-10:2010
Subacute/SubChronic Toxicity	ISO 10993-11:2006
Genotoxicity	ISO 10993-3:2014

5.11 CONCLUSION

Overall, the Indications for Use statement for the Subject and Predicate devices are substantially equivalent.

Overall, the Technological Characteristics, Materials, Prescription Use and Non-sterile status of the Subject device are substantially equivalent to the Predicate device. The use of Software to produce the Subject and Predicate devices is substantially equivalent.

Overall, the 3D Smile Predict aligners are substantially equivalent to the Predicate device.