Smile Development Corp
Ian Kitching
President & CEO
7179 Cherrywood Ct
Highland, California 92346

January 19, 2018

Re: K171674
Trade/Device Name: Angel Align System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: December 6, 2017
Received: December 11, 2017

Dear Ian Kitching:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5. Indications for Use Statement (FDA Form 3881)

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)*
K171674

Device Name
Angel Align

Indications for Use *(Describe)*
Angel Align System is 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.

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

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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

6. 510(k) Summary

510(k) SUMMARY

510(k) Owner	Smile Development Corp. 7179 Cherrywood Court Highland, CA 92346 Phone: 408.621.1152
Contact person	Ian Kitching Smile Development Corp. 7179 Cherrywood Court Highland, CA 92346 Phone: 408.621.1152 ian@smiledevcorp.com
Submission Date	December 11, 2017
Product Code:	
Common Name	Orthodontic Plastic Brackets
Trade Name	Angel Align System
Classification Name	aligner, sequential
Regulation	872.5470
Class	Class II
Panel	Dental
Product Code	NXC
Predicate	K143630 Invisalign – Align Technology, Inc.

Description

The Angel Align System consists of a series of doctor-prescribed, thin, clear plastic removable orthodontic appliances (aligners) and proprietary 3D software. The aligners gently move the patient's teeth in small increments from their original state to a more optimal, treated state.

The Angel Align System is intended as an alternative to conventional wire/bracket technology and fixed appliances for the treatment of patients with malocclusion.

The 3D software generates the model of a provisional treated state and then creates a series of models that represent intermediate teeth states. The dental practitioner reviews these models to view, edit or approve the orthodontic treatment plan. The dental practitioner has the option to

reject or request modifications to the set-up prior to approving it for aligner fabrication. Once the doctor approves the set-up, the series of custom-made aligners are manufactured, packaged, and shipped to the dental practitioner to be dispensed to the patient for treatment.

Indications for Use

Angel Align System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.

Technological Characteristics

The predicate and the Angel Align System were compared in the following areas and found to have similar technological characteristics and to be equivalent:

Device Comparison Table

	Angel Align System	K143630
Intended Use Statement	**SAME** The Angel Align System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.	**SAME** The Invisalign System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.
3-D Software Description	**SAME** The Angel Align 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	**SAME** The Align 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, 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
Mode of Operation for 3-D Software	**SAME** Angel Align 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 software and has the option to reject or request modifications to the set-up prior to approval.	**SAME** Invisalign 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 ClinCheck software and has the option to reject or request modifications to the set-up prior to approval.

Material	**SAME** 0.03" thick, thermoformed polyurethane	The Invisalign System uses either: **DIFFERENT** 1. 0.03" thick, Multilayer aromatic thermoplastic polyurethane / copolyester. or: **SAME** 2. 0.03" thick, thermoformed polyurethane
Mode of Use	**SAME** 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.	**SAME** 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.
Description of Appliance Application	**SAME** Removable	**SAME** Removable
Manufacturing Method	**SAME** A digital model of the patient's teeth is created from either CT scanning a PVS impression or directly from an intraoral scan of the patient's teeth. From the digital model, following a dental practitioner's prescription, the software generates model transforms describing the provisional final, treated state and then interpolates a series of model transforms that represent intermediate states of alignment. The resulting computer "setups" relay this information to rapid prototyping machines that produce physical positive models. The aligners are produced by thermoforming on each physical model to fabricate the sequence of aligners.	**SAME** A digital model of the patient's teeth is created from either CT scanning a PVS impression or directly from an intraoral scan of the patient's teeth. From the digital model, following a dental practitioner's prescription, the software generates model transforms describing the final, treated state and then interpolates a series of model transforms that represent intermediate states of alignment. The resulting computer "setups" relay this information to rapid prototyping machines that produce physical positive models. The aligners are produced by thermoforming on each physical model to fabricate the sequence of aligners.

The predicate and the Angel Align System were compared in the following area and found to have minor different technological characteristics. The following differences have been determined to not have any impact on the safety or efficacy of the Angel Align System:

	Angel Align System	K143630
Material	**SAME** 0.03" thick, thermoformed polyurethane	The Invisalign System uses either: **DIFFERENT** 1. 0.03" thick, Multilayer aromatic thermoplastic polyurethane / copolyester. or: **SAME** 2. 0.03" thick, thermoformed polyurethane

The following non-clinical performance tests were conducted:

Software Validation	PASS
Design Verification and Validation	PASS
ISO10993	PASS

Conclusions from non-clinical performance data

After performing non-clinical performance studies, the data shows that the Angel Align System is substantially equivalent to the predicate as a sequential aligner.

The following post market clinical data was submitted for clinical performance data:

Post-Market Study	PASS

Conclusions from the clinical data

The data provides evidence of safety and effectiveness for all tooth movements and demonstrates that the Angel Align System is substantially equivalent to the predicate as a sequential aligner.