Align Technology, Inc.
Somi Ekwealor
Sr. Regulatory Affairs Analyst
2820 Orchard Pkwy
San Jose, California 95134

October 26, 2018

Re: K181739
Trade/Device Name: Invisalign System with Mandibular Advancement Feature
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: September 7, 2018
Received: September 10, 2018

Dear Somi Ekwealor:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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 -S3

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

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)*
K181739

Device Name
Invisalign System with Mandibular Advancement Feature

Indications for Use *(Describe)*
The Invisalign System is indicated for the 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

General Information

510(k) Sponsor	Align Technology, Inc.
Address	2820 Orchard Parkway San Jose, CA 95134
FDA Registration Number	2953749
Correspondence Person	Mr. Somi Ekwealor, MSRS, RAC Sr. Regulatory Affairs Analyst Align Technology, Inc.
Contact Information	Email: sekwealor@aligntech.com Phone: (408) 470-1432 Fax: (408) 470-1011
Date Prepared	29 June 2018

Device Identification

Proposed Device:

Proprietary Name	Invisalign System with Mandibular Advancement Feature
Common Name	Aligner, Sequential
Classification Name	Orthodontic Plastic Bracket
Regulation Number	21 CFR 872.5470
Product Code	NXC
Regulatory Class	II

Predicate Device:

Proprietary Name	Invisalign Orthodontic System
Common Name	Aligner, Sequential
Premarket Notification	K143630
Classification Name	Orthodontic Plastic Bracket
Regulation Number	21 CFR 872.5470
Product Code	NXC
Regulatory Class	II

Device Description
This premarket notification is submitted to notify the FDA of Align Technology's intent to market the Invisalign System with Mandibular Advancement Feature (MAF) (hereafter referred to as "Proposed Device"). The Proposed Device is a minor change to the currently marketed Invisalign System (K143630) (hereafter referred to as "Predicate Device") to support repositioning of the mandible.

Invisalign System with Mandibular Advancement Feature consists of a series of doctor prescribed, customized, thin, clear plastic, removable orthodontic appliances (aligners) and proprietary ClinCheck 3-D software. The aligners gently move the patient's teeth in small increments and position the mandible forward from their original state to a more optimal, treated state. The Proposed Device treats patients with Class 1 and Class 2 malocclusion as well as patients with severe open bite, severe overjet, deep bite, skeletally narrow jaw, dental prostheses/implants, and/or those who require surgical correction. The Proposed Device includes two mandibular advancement features, also known as "precision wings", on each upper and lower aligner that function as mandibular repositioners, maintaining the lower jaw in the forward position.

The Proposed Device is made from the same material and utilizes the same manufacturing processes as the Predicate Device, Invisalign System (K143630). The software level of concern for the Predicate Device is moderate. Minor updates have been made to the proprietary ClinCheck 3-D software to enable placement of the mandibular advancement features on the aligners during the MA Phase of treatment. The software level of concern for the Proposed Device is determined to be the same as the Predicate Device: moderate.

Intended Use/Indications for Use
The Invisalign System is intended for the orthodontic treatment of malocclusion.

Comparison of Technological Characteristics with the Predicate Device
The Proposed Device and Predicate Device are similar in indications for use, intended use, technological characteristics, and principles of operation. The materials of the Proposed Device are identical to those used in the Predicate Device.

The differences between the Proposed Device and the Predicate Device are minor and raise no different questions of safety and effectiveness, thus it was concluded that the Proposed Device is substantially equivalent to the Predicate Device. In accordance with 21CFR807.92(a)(6) a summary of how the technological characteristics of the Proposed Device compares to the Predicate Device is provided below.

Differences between the Predicate and Proposed Devices

Comparison Criteria	Predicate Device (K143630)	Proposed Device	Comparison Assessment
Intended Use/Indications for Use			
Indication for Use	Indicated for the alignment of teeth during orthodontic treatment of malocclusion	Indicated for the orthodontic treatment of malocclusion.	Similar
In Use Duration	Aligners are worn for approximately 2 weeks of 20-22 hours of wear per day, after which it is replaced by the next stage aligners. This is repeated for duration as prescribed by the Dental Practitioner.	Aligners are worn for approximately 1-2 weeks of 20-22 hours of wear per day, after which it is replaced by the next stage aligners. This is repeated for duration as prescribed by the Dental Practitioner.	Similar
Design			
Operating Principle	Sequential aligners apply continuous gentle force to the teeth	Sequential aligners apply continuous gentle force to the teeth and position the mandible forward	Different
Lower Jaw Adjustment Mechanism	N/A	Mandibular Advancement Features also known as "Precision Wings"	Different

Indications for Use

The Proposed Device allows dental practitioners to prescribe a Mandibular Advancement Phase (MA Phase) during Invisalign Orthodontic Treatment using mandibular advancement features or "precision wings". Clinical and nonclinical data are provided to support the safety and effectiveness of the change in indication for use.

This minor difference in the Proposed Device does not introduce additional risks and raises no different questions of safety or effectiveness thus demonstrating substantial equivalence to the Predicate Device.

In Use Duration

The dental practitioner shall prescribe the appropriate aligner wear time for the patient. The appropriate testing was performed to support the 1-2 week wear time.

This minor difference in the Proposed Device does not introduce additional risks and raises no different questions of safety or effectiveness thus demonstrating substantial equivalence to the Predicate Device.

Operating Principle

The Proposed Device is a minor change to the Predicate Device to support mandibular advancement during Mandibular Advancement (MA) Phase of Invisalign Orthodontic Treatment. Clinical data is provided to support the safety and effectiveness of the operating principle of the Proposed Device.

This minor difference in the Proposed Device does not introduce additional risks and raises no different questions of safety or effectiveness thus demonstrating substantial equivalence to the Predicate Device.

Lower Jaw Adjustment Mechanism

The Proposed Device is a minor change to the Predicate Device to support repositioning of the mandible. The mandibular advancement features, also known as "precision wings", are what support the advancement of the mandible. They are designed to engage the upper and lower aligners so that the mandible is held in a more protrusive position as needed for treatment. Clinical and nonclinical data are provided to support the safety and effectiveness of the lower jaw adjustment mechanism of the Proposed Device.

Performance Testing

The Invisalign System with Mandibular Advancement Feature was tested for performance in accordance with internal design specification and with the applicable performance standards, which support the substantial equivalence determination. The following performance tests were conducted and are summarized in this premarket notification:

Performance Testing Summary

Test Name	Description
Clinical Performance	Validates clinical safety and effectiveness in treating growing pediatric patients who present up to full cusp dental and skeletal Class 2 malocclusions using Invisalign System with Mandibular Advancement Feature
Aligner Geometry	Verifies that Invisalign System with Mandibular Advancement Feature has adequate geometry and definition of the dentition.
Force System	Verifies that the Invisalign System with Mandibular Advancement Feature meet the defined performance requirements for the movements programmed for the dentition.
Cyclic Fatigue – Normal Use Loads	Verifies Invisalign System with Mandibular Advancement Feature maintains integrity during normal use (e.g. while talking).
Cyclic Fatigue – Misuse Loads	Verifies that intentional or accidental misuse of the Invisalign System with Mandibular Advancement Feature is not a risk to the patient.
Biocompatibility	Verifies the biocompatibility of the permanent contact device in accordance with ISO 10993-1:2009.

Biocompatibility was assessed in accordance with ISO 10993-1:2009 "Biological Evaluation of Medical Devices — Part 1: Evaluation and Testing within a Risk Management Process", FDA

Guidance *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"*, issued on June 16, 2016, and related collateral standards for patient contacting materials.

Nonclinical performance testing was conducted to ensure that the device functioned as intended and met design specifications and acceptance criteria. Test results obtained verified the safety and effectiveness of the Proposed Device per design specifications and applicable standards.

Clinical Testing

Align conducted an FDA-approved, endpoint driven clinical study for the Proposed Device at multiple sites to demonstrate clinical safety and effectiveness, and to gather data for marketing claims. The results of the study confirm the Proposed Device is a safe and effective means of correcting skeletal and dental class 2 malocclusions. No adverse events occurred in this study.

Conclusion

The materials of the Proposed Device are identical to those used in the Predicate Device. The Proposed Device is similar to the Predicate Device in indications for use, intended use, technological characteristics, and principles of operation. Based on the nonclinical and clinical testing performed related to the minor differences discussed, the Invisalign System with Mandibular Advancement Feature does not introduce new risks and raises no different questions of safety and effectiveness, thus demonstrating substantial equivalence.