April 7, 2022

Align Technology, Inc.
Shweta Daga
Director, Regulatory Affairs
2820 Orchard Parkway
San Jose, California 95134

Re: K220287
Trade/Device Name: Invisalign System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: March 10, 2022
Received: March 11, 2022

Dear Shweta Daga:

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, 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)*
K220287

Device Name

Invisalign System

Indications for Use *(Describe)*

The Invisalign System is intended 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

Align Technology's Invisalign System

General Information

510(k) Sponsor	Align Technology, Inc.
Address	2820 Orchard Parkway San Jose, CA 95134
FDA Registration Number	2953749
Contact Person	Shweta Daga Director, Regulatory Affairs Align Technology, Inc.
Contact Information	Email: sdaga@aligntech.com Phone: +1 408-470-1000 Fax: +1408-470-1010
Date Prepared	Jan 31, 2022

Name of Device and Name/Address of Sponsor

Name of Device	Invisalign System
Name/Address of Sponsor	Align Technology, Inc. 2820 Orchard Parkway San Jose, CA 95134
Trade/Proprietary Name	Invisalign System
Common Name	Aligner, Sequential
Classification Name	Orthodontic Plastic Bracket

Predicate Device

Name of Device	Invisalign System with Mandibular Advancement Feature (MAF)
Name/Address of Sponsor	Align Technology, Inc. 2820 Orchard Parkway San Jose, CA 95134
Trade/Proprietary Name	Invisalign System with Mandibular Advancement Feature
Common Name	Aligner, Sequential
Classification Name	Orthodontic Plastic Bracket

Purpose of the Special 510(k) notice.

The purpose of this Special 510(k) notice is to request clearance for proposed changes related to labeling material which include the Doctor's Instructions for Use (IFU), and Patient's IFU, with minor changes and clarifications made based on post-market data. Additionally, this Special 510(k) pre-market notification describes all non-significant changes implemented through documentation since the last 510(k) clearance.

Intended Use

The Invisalign System is indicated for the orthodontic treatment of malocclusion.

Device Description

The Invisalign System (subject device) consists of removable orthodontic appliances (aligners), proprietary 3D software and attachment template. The system consists of a series of doctor prescribed, customized, thin, clear plastic aligners that gently move the patient's teeth in small increments from their original state to a more optimal, treated state to address malocclusion. The optional mandibular advancement feature positions patients jaw forward to address skeletal malocclusion. The system is used in patients with primary, mixed, and permanent dentition.
The Invisalign System is intended for treating dental and skeletal malocclusion in patients with Class I, II and III including Antoro-Posterior (A-P), vertical (open bite, deep bite), transverse (narrow arch or jaw, crossbite), or inter-arch (spacing and crowding) correction at all severity levels. In some cases, surgical intervention, or addition of other appliances in addition to Invisalign treatment may be needed at the doctor's discretion.

The Invisalign System aligners consist of a series of customized orthodontic devices made from proprietary thermoformed polyurethane sheeting material. The first device in the series matches the patient's dentition in its current state and then each subsequent aligner stage has the shape of the dentition shifted gradually toward the final desired position. The aligners can accommodate use of tooth attachments and elastics (through use of precision cut outs or buttons or power arms). The system can also be ordered with additional aligner features such as precision cut outs, bite ramps, compliance indicators, and mandibular advancement features (MAF). MAF is also referred to as precision wings and is prescribed by the dental practitioner to position the lower jaw forward during correction of skeletal malocclusion. The subject device system of this Special 510(k), referred to as the Invisalign System, is a modification to the predicate device the Invisalign System with Mandibular Advancement Feature (MAF) (K181739, cleared on Oct 26, 2018) and is inclusive of both standard aligners and aligners with mandibular advancement feature.

The proprietary ClinCheck (CC) 3-D software is inclusive of both dental practitioner-facing functions and internal Align personnel-facing functions. The Align personnel-facing functions are termed 'Treat' internally. This internal facing software enables Align's computer-aided design (CAD) designers to create a treatment plan based on a doctor's prescription and inputs (e.g., dental scans). The treatment plans created using the Align personnel-facing software are then reviewed and approved by doctors before the aligners are manufactured. The doctors' reviews and approvals are exchanged via ClinCheck software (dental practitioner-facing software). Once the treatment plan is approved by the dental practitioner, the information is sent to the manufacturing facility for creation of the aligners.

When attachments are prescribed as part of the treatment plan, a disposable template is provided to assist the dental practitioner in positioning and forming the attachments from dental composite (sold separately). Attachment templates are disposable polyurethane appliances which match the patient's existing dentition and include wells for the placement of dental composite. During the first

visit, the dental practitioner uses the template in bonding dental composite to the tooth surface to create attachments on the teeth. These attachments help create forces on the tooth which can assist in aligner retention or optimized aligner force system for tooth movement.

All these components and features were available with the predicate device.

Comparison with Predicate Device

Proposed modified device and predicate device have the same indications for use, intended use, technological characteristics, and principle of operation. The material of the Modified Device is identical to the Predicate Device.

The differences between the modified device and the predicate device are minor labeling updates which do not raise any questions regarding safety and effectiveness. In accordance with 21 CFR 807.92(a)(6) a summary of the technological characteristics' comparison of the proposed modified device to the predicate Device is provided below.

Technological Characteristics comparison with the Predicate Device

The Invisalign System (subject device) has no proposed changes to its technological characteristics. The proposed labeling changes do not alter any technological characteristics and do not impact the current safety and effectiveness profile of the Invisalign System.

The Invisalign System with minor modifications implemented to date through documentation to file has similar technological characteristics as the predicate device - Invisalign System with Mandibular Advancement Feature (cleared in K181739). The material and mode of action are unchanged and no new aligner features have been introduced.

Comparison Criteria	Subject/ Modified Device	Predicate/ Existing Device (K181739)	Comparison Assessment
Intended Use/Indications for Use			
Indications for Use	The Invisalign System is intended for the orthodontic treatment of malocclusion.	The Invisalign System is intended for the orthodontic treatment of malocclusion.	Same as predicate device
In Use Duration	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.	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.	Same as predicate device
Patient Population	Children, Adolescents and Adults	Pediatrics and Adults	Same as predicate device
Use Location	Dental intraoral Devices	Dental intraoral Devices	Same as predicate device
OTC or Prescription (Rx) Device	Rx only	Rx only	Same as predicate device

Comparison Criteria	Subject/ Modified Device	Predicate/ Existing Device (K181739)	Comparison Assessment
Design			
Operating Principle	**Aligners:** Sequential aligners apply continuous gentle force to the teeth and/or position mandible forward. **3D Software:** Produces 3D-model file of the PVS impression or the digital scan. Identifies the individual teeth that require treatment (i.e., repositioning). Creates a treatment plan (i.e., 3-D models that represent the treatment plan) which is reviewed by the treating dental practitioner using ClinCheck's doctor facing function to reject or request modifications to the set-up prior to approval.	**Aligners**: Sequential aligners apply continuous gentle force to the teeth and position mandible forward **3D Software: Produces** 3D-model file of the PVS impression or the digital scan. Identifies the individual teeth that require treatment (i.e., repositioning). Creates a treatment plan (i.e., 3-D models that represent the treatment plan) which is reviewed by the treating dental practitioner using ClinCheck's doctor facing function to reject or request modifications to the set-up prior to approval.	Same as predicate device Note, mandible advancement feature such as precision wings is an optional feature offered through the predicate device.
Materials	Thermoplastic polymer	Thermoplastic polymer	Same as predicate device
Lower Jaw Adjustment Mechanism	Invisalign System aligners with mandibular advancement feature (MAF) such as enhanced precision wings with a curved design. For Invisalign system with standard aligners this is not applicable.	Invisalign System Mandibular Advancement Feature wings such as enhanced precision wings with a curved design	Same as predicate device Note, mandible advancement feature such as precision wings is an optional feature offered through predicate device.

Performance Data

There are no proposed design changes in the scope of this pre-market notification. The proposed labelling changes do not trigger any performance testing as the changes are minor clarifications and additions that do not impact the current safety and effectiveness profile of the Invisalign System. No animal or clinical testing was required to validate these labeling modifications.

Substantial Equivalence

The Invisalign System (Subject Device) and the previously cleared predicate Invisalign System with Mandibular Advancement are similar in that they have:

- same intended use,
- same indications for use,
- same principles of operation, and
- same technological characteristics.

The primary change introduced to the Invisalign System through the Special 510(k) submission is proposed labeling updates to the doctor and patient instruction for use. There are no proposed design changes as part of this submission.

Conclusion

Align Technology's Invisalign System has the same intended use and indications for use as the previously cleared Invisalign System with Mandibular Advancement Feature (MAF) (K181739). In addition, the Invisalign System has the same technological characteristics, and principles of operation as its predicate. The minor labeling differences between the Invisalign System and its predicate device do not raise new questions of safety or efficacy. Thus, the Invisalign System is substantially equivalent.