December 22, 2022

Align Technology, Inc.
John Ray
Principal, Regulatory Affairs
2820 Orchard Parkway
San Jose, California 95134

Re: K222894
Trade/Device Name: Invisalign System, Pre-Formed Attachment System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: September 23, 2022
Received: September 23, 2022

Dear John Ray:

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 -S

Michael E. Adjodha, M. ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
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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)*
K222894

Device Name
Invisalign System with Pre-Formed Attachment 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.

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Section 7: 510(K) Summary

Align Technology's Invisalign System with Pre-Formed Attachment System

General Information

510(k) Sponsor	Align Technology, Inc.
Address	2820 Orchard Parkway San Jose, CA 95134
FDA Registration Number	2953749
Contact Person	Manjunath Bisalehalli Manager, Regulatory Affairs Align Technology, Inc. cc: Shweta Daga Director, Regulatory Affairs Align Technology Inc.
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Date Prepared	September 23, 2022

Name of Modified Device and Name/Address of Sponsor

Name of Device	Invisalign System with Pre-Formed Attachment System
Name/Address of Sponsor	Align Technology, Inc. 2820 Orchard Parkway, San Jose, CA 95134
Trade/Proprietary Name	Invisalign System Pre-Formed Attachment System
Common Name	Aligner, Sequential
Classification Name	Orthodontic Plastic Bracket
Regulation Number	21 CFR 872.5470
Product Code	NXC
Regulatory Class	II

Predicate Device

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
Regulation Number	21 CFR 872.5470
Product Code	NXC
Regulatory Class	II

Purpose of the Traditional 510(k) notice

The purpose of this Traditional 510(k) notice is to request clearance for the addition of Pre-Formed Attachment (PFA) System to the Invisalign System's existing components. The PFA system is an optional alternative attachments bonding mechanism for Invisalign treatment.

Additionally, the Traditional 510(k) introduces the proprietary, 3D device-generation manufacturing software, labeling documentation associated with the PFA system, and the non-significant changes to the Invisalign System implemented through documentation since the last 510(k) clearance.

Intended Use

The Invisalign System with the Pre-Formed Attachment System (Modified device) has the same intended use as the cleared Predicate device, the Invisalign System (K220287), which is as follows:

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

Device Description

The subject device, Invisalign System with Pre-Formed Attachments (PFA) System, is a modification to the predicate device, the Invisalign System (K220287, cleared on April 7th, 2022). The Invisalign System with PFA system consists of removable orthodontic appliances (aligners), proprietary treatment planning 3D software, attachment templates and/or PFA system.

Like the predicate device, the Invisalign system with PFA (subject device) 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 dental malocclusion. The Invisalign system aligners are used in patients with primary, mixed (primary and permanent), and permanent dentition. The Invisalign system aligners with mandibular advancement feature(s) are used in patients with mixed and permanent dentition to correct Class II malocclusions. The Invisalign system is intended to treat dental and skeletal malocclusion in patients with Class I, II and III including Antero-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 proprietary ClinCheck (CC) 3-D software is inclusive of both dental practitioner-facing functions and internal Align personnel-facing functions. The Align 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, the subject device has the option of delivering them preformed with PFA system or with a disposable attachment template. The attachment templates are disposable polyurethane appliances which match the patient's existing dentition and include wells for the placement of dental composite (sold separately). 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 aligner retention or optimized aligner force system for tooth movement.

The PFAs are made of a fully cured proprietary photo-polymerizable methacrylate-based resin (similar to dental composite material). PFA system is intended to enable correct placement of attachments and bond attachments to the tooth surface for aligner retention and to optimize aligner force system for tooth movement.

The patient-customized PFA are manufactured using additive manufacturing technologies and configured to individual patient's treatment plans and teeth anatomy using a proprietary internal facing 3D device-generation manufacturing software.

Comparison with Predicate Device

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 with Pre-Formed Attachment (PFA) System (subject device) introduces an alternative attachment delivery mechanism to Invisalign treatment. The proposed change does not alter the aligners' technological characteristics and does not impact the current safety and effectiveness profile of the Invisalign System.

	Invisalign System with PFA System Subject/Modified Device	Invisalign System (K220287) Predicate/ Existing Device	Comparison Assessment
Indication for Use, User Population			
Intended Use/ Indication 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
Patient Population	Children, Adolescents and Adults	Children, Adolescents 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
Technological Characteristics			
Principle of Operation	**Aligners**: Sequential aligners apply continuous gentle force to the teeth and/or position mandible forward.	**Aligners**: Sequential aligners apply continuous gentle force to the teeth and position mandible forward	**Same** as predicate device
	3D Software: Produces 3D-model file of the PVS impression or the digital scan. Identifies the individual teeth that requires 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.	**3D Software**: Produces 3D-model file of the PVS impression or the digital scan. Identifies the individual teeth that requires 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
	Delivery Mechanism of Attachment		
	1) Attachment Template - Bonds dental composite (material provided by doctor) to the tooth surface to create attachments used for aligner retention or optimized aligner	**1) Attachment Template -** Bonds dental composite (material provided by doctor) to the tooth surface to create attachments used for aligner retention or optimized aligner	**Same** as predicate device

	Invisalign System with PFA System Subject/Modified Device	Invisalign System (K220287) Predicate/ Existing Device	Comparison Assessment
	force system for tooth movement. Delivery Mechanism: formed by dental practitioner who fills and packs wells in the Template tray with commercially available dental composite. The final shape & configuration is cured when tray is seated on dentition.	force system for tooth movement. Delivery Mechanism: formed by dental practitioner who fills and packs wells in the Template tray with commercially available dental composite. The final shape & configuration is cured when tray is seated on dentition.	
	2) PFA System – enables correct placement of attachments and bond attachments to the tooth surface for aligner retention and to optimize aligner force for tooth movement. Delivery of Mechanism: the attachment shape and configuration defined by the treatment plan, manufactured together with positioner. The shapes are cured to the tooth when the positioner is seated on dentition	2) Not applicable	**Similar** to predicate device The attachment configuration prescribed by treatment is identical to the predicate device, however the mechanism of delivery attachments onto the dentition is different. Therefore, the subject device is substantially equivalent to the predicate device
Material	**Aligners and Attachment Templates** - Thermoplastic polymer	**Aligners and Attachment Templates** - Thermoplastic polymer	**Same** as predicate device
	PFA System - Photo-polymerizable methacrylate-based resin	Not applicable	**Similar** to predicate device Although the material is different when the alternative attachment delivery mechanism, pre-formed attachments, is prescribed by the Doctor. The pre-formed attachments material is biocompatible and has demonstrated that it can deliver the force system with the Invisalign System.
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 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.	**Same** as predicate device

Performance Data

The existing Invisalign System's components: aligners, 3D software and attachment template, remain unchanged from the predicate device. The newly added PFA system as an optional alternative attachment delivery mechanism, underwent a complete set of functional and performance testing; including, but not limited to bond strength, stain resistance, wear, force measurement, volume precision, and usability testing. Based on the performance testing outcomes, the proposed addition of PFA system does not impact the current safety and effectiveness profile of the Invisalign System and is substantially equivalent to the predicate device.

No animal or clinical testing was required to validate these modifications implemented to the Invisalign System.

Biocompatibility

The existing Invisalign System's components: aligners, 3D software and attachment template, remain unchanged from the predicate device. Biocompatibility testing was completed for the proposed PFA system and assessed in accordance with ISO 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process, and ISO 7405, Dentistry — Evaluation of biocompatibility of medical devices used in dentistry. The results demonstrate that the PFA system does not pose any significant biologicals risks and is considered safe for its intended use in humans.

Software Testing

In accordance with IEC 62304, Medical device software – Software life cycle processes; successful software verification and validation (V&V) testing at the unit, integration, and system level was performed to qualify the newly added software with the subject device.

Substantial Equivalence

The subject device is a modification to the predicate device, Invisalign System (K220287), which was cleared on April 7th, 2022. The subject device and the previously cleared predicate device are similar in that they have:

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

The minor differences in the principles of operation and technological characteristics between the subject device and predicate device do not raise different questions of safety or efficacy. Therefore, the subject device is found to be substantially equivalent to the legally marketed predicate device, Invisalign System (K220287).

Conclusion

Align Technology's Invisalign system with the PFA system has the same intended use and indications for use as the previously cleared Invisalign system (K220287). The minor principles of operation and technological differences between the subject device and its predicate device do not raise new issues of safety or effectiveness. Performance data and biocompatibility testing demonstrate that the subject device is as safe and effective as the predicate Invisalign System. Thus, the modified Invisalign system with PFA system is substantially equivalent to the predicate device.