September 26, 2023

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

Re: K232233
Trade/Device Name: Invisalign System with Mandibular Advancement Featuring Occlusal Blocks
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: July 26, 2023
Received: July 27, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., CQIA
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

Section 6: Indications for Use Statement

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)*

K232233

Device Name

Invisalign System with Mandibular Advancement Featuring Occlusal Blocks (OB)

Indications for Use *(Describe)*

The Invisalign System is intended for the orthodontic treatment of malocclusion in patients with primary, mixed (primary and permanent), or permanent dentition. The optional mandibular advancement feature(s) are indicated for the treatment of skeletal malocclusion in patients with mixed or permanent dentition.

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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Align Technology

Invisalign System with Mandibular Advancement Featuring Occlusal Blocks Traditional 510(k)

Section 7: 510(K) Summary

Section 7: 510(K) Summary

K232233

Align Technology's Invisalign System with Mandibular Advancement Featuring Occlusal Blocks

General Information

510(k) Sponsor	Align Technology, Inc.
Address	2820 Orchard Parkway San Jose, CA 95134
FDA Registration Number	2953749
Contact Person	John Ray Principal, Regulatory Affairs Align Technology, Inc. cc: Shweta Daga Director, Regulatory Affairs Align Technology Inc.
Contact Information	Email: jray@aligntech.com Cell Phone: +1 425-985-8061
Date Prepared	July 28, 2023

Name of Modified Device and Name/Address of Sponsor

Name of Device	Invisalign System with Mandibular Advancement Featuring Occlusal Blocks
Name/Address of Sponsor	Align Technology, Inc. 2820 Orchard Parkway, San Jose, CA 95134
Trade/Proprietary Name	Invisalign System with Mandibular Advancement Featuring Occlusal Blocks
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
510(k) number	K220287

Reference Device

Name of Device	Invisalign System with Mandibular Advancement Feature
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
510(k) number	K181739

Purpose of the Traditional 510(k) notice

The purpose of this Traditional 510(k) notice is to request clearance for the addition of the Invisalign System with Mandibular Advancement Featuring Occlusal Blocks. The Invisalign System with Mandibular Advancement Featuring Occlusal Blocks is an optional feature for advancing the mandible (lower jaw) in patients with Class 1 and 2 malocclusions, in conjunction with severe open bite, severe overjet, deep bite, skeletally narrow jaw, and/or those patients requiring surgical correction

Additionally, this Traditional 510(k) introduces the proprietary, 3D treatment planning software and labeling documentation associated with the subject device, and all non-significant changes implemented to the Invisalign System implemented through documentation since the last 510(k) clearance.

Indications for Use

The Invisalign System with Mandibular Advancement Featuring Occlusal Blocks, (subject device) has similar indications for use as the cleared predicate device, the Invisalign System (K220287), which is as follows:

The Invisalign System is intended for the orthodontic treatment of malocclusion in patients with primary, mixed (primary and permanent), or permanent dentition. The optional mandibular advancement feature(s) are indicated for the treatment of skeletal malocclusion in patients with mixed or permanent dentition.

Device Description

The subject device, Invisalign System with Mandibular Advancement Featuring Occlusal Blocks (Invisalign System, MAOB) is a modification to the predicate device, Invisalign System

(K220287, cleared on April 07, 2022) and the reference device, Invisalign System with Mandibular Advancement Features (K181739, cleared on October 26th, 2018). The Invisalign System, MAOB (subject device) consists of removable orthodontic appliances (aligners with mandibular advancement features including occlusal blocks), proprietary treatment planning 3D software (doctor facing - ClinCheck and Align employee facing -Treat) and attachment templates. The scope of this premarket submission is:

- addition of aligners with occlusal blocks to induce mandibular skeletal changes in the treatment of Class 1 and 2 malocclusions, in conjunction with severe open bite, severe overjet, deep bite, skeletally narrow jaw, and/or those patients requiring surgical correction. Invisalign aligners with occlusal blocks are another design/feature under previously cleared Invisalign System with Mandibular Advancement Feature such as Enhanced Precision Wings (K220287).

Like the predicate device, the Invisalign System with Mandibular Advancement Featuring Occlusal Blocks 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 and skeletal malocclusion. The Invisalign System is used in patients with primary, mixed (primary and permanent), or permanent dentition. The Invisalign System with mandibular advancement feature(s) such as precision wings (predicate device) and occlusal blocks (subject device) are used in patients with mixed or permanent dentition to correct Class I and II malocclusions. The Invisalign System is used to treat Class I and II dental and skeletal malocclusion in patients with 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 Invisalign System's proprietary 3-D software is inclusive of both dental practitioner-facing functions (ClinCheck Pro 6) and internal Align personnel-facing functions (Treat). The Align facing software enables Align 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 doctor reviews, optionally modifies, and approves the treatment plans using 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 Invisalign treatment plan, a disposable template is provided to assist the dental practitioner in positioning and bonding the attachments from commercial dental composite. Attachment templates are disposable polyurethane accessory 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 and Reference Devices

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 Mandibular Advancement Featuring Occlusal Blocks (subject device) introduces an alternative feature for mandibular advancement. 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 Mandibular Advancement Featuring Occlusal Blocks Subject/Modified Device	**Invisalign System (K220287) Predicate Device**	**Invisalign System with Mandibular Advancement Feature (K181739) Reference Device**	**Comparison Assessment**
Indication for Use, User Population				
Indication for Use	The Invisalign System is intended for the orthodontic treatment of malocclusion in patients with primary, mixed (primary and permanent), or permanent dentition. The optional mandibular advancement feature(s) are indicated for the treatment of skeletal malocclusion in patients with mixed or permanent dentition.	The Invisalign System is intended for the orthodontic treatment of malocclusion.	The Invisalign System is intended for the orthodontic treatment of malocclusion.	**Similar** to predicate device. See Section 13 for discussion of non-significant changes.
Patient Population	Children, Adolescents and Adults	Children, Adolescents and Adults	Pediatrics and Adults	**Same** as predicate device
Use Location	Dental intraoral Devices	Dental intraoral Devices	Dental intraoral Devices	**Same** as predicate device
OTC or Prescription (Rx) Device	Rx only	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	**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	**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	**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)	**Same** as predicate device

	Invisalign System with Mandibular Advancement Featuring Occlusal Blocks Subject/Modified Device	Invisalign System (K220287) Predicate Device	Invisalign System with Mandibular Advancement Feature (K181739) Reference Device	Comparison Assessment
	ClinCheck's doctor facing function to reject or request modifications to the set-up prior to approval.	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.	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.	
Mandibular Advancement Feature	Occlusal blocks	Enhanced precision wings	Precision wings	**Similar** to predicate device Occlusal block features added to achieve same clinical outcomes as predicate device
Aligner Materials	Thermoplastic polymer	Thermoplastic polymer	Thermoplastic polymer	**Same** as predicate device
Mandibular Advancement Feature materials	Thermoplastic polymer and coating material used in manufacturing	Thermoplastic polymer	Thermoplastic polymer	**Similar** to predicate device. Addition of coating material to aid in manufacturing .
Performance Testing				
Durability (Normal Use)	The Invisalign System, MAOB sustained cyclic loading without breakages.	Same design as Reference Device (repeat testing not required)	The Invisalign System with MA sustained cyclic loading without breakages.	**Same** as predicate device
Durability (Misuse Loading)	The Invisalign System with MAOB survived without catastrophic failure.	The Invisalign System with MA survived without catastrophic failure.	The Invisalign System with MA survived without catastrophic failure.	**Same** as predicate device
Force Measurement Apparatus	Force mechanical verification testing demonstrated that the Invisalign System, MAOB provides adequate force on teeth.	Same design as Reference Device (repeat testing not required)	Force mechanical verification testing demonstrated that the Invisalign System provides adequate force on teeth.	**Similar** as predicate device.
Bioburden	Bioburden testing per ISO 11737-1	Bioburden testing per ISO 11737-1	Bioburden testing per ISO 11737-1	**Same** as predicate device
Packaging	Packaging validation testing per ISTA3A	Packaging validation testing per ISTA3A	Packaging validation testing per ISTA3A	**Same** as predicate device

Performance Data

Bench testing was completed consistent with testing completed for the predicate device system (K220287). In addition, specific bench testing was completed to verify that Invisalign aligners with occlusal block features remain functionally intact and safe, and meet their requirements, when exposed to cycles simulating normal use, wear time, and excessive force misuse. No animal or clinical testing was required or performed for Invisalign System with Mandibular Advancement Featuring Occlusal Blocks.

Biocompatibility

The Invisalign System with Mandibular Advancement Featuring Occlusal Blocks is categorized as a long-term surface device with mucosal contact. Biological risk assessment was performed, and subsequent biocompatibility testing was successfully completed per the ISO 10993 suite of standards. The subject device was found to be non-cytotoxic, non-sensitizer, non-irritating, non-pyrogenic, non-toxic, and non-genotoxic per biocompatibility testing.

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

The minor differences in the indications for use, 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 Mandibular Advancement Featuring Occlusal Blocks has the same intended use and similar 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 Mandibular Advancement Featuring Occlusal Blocks is substantially equivalent to the predicate device.