December 15, 2023

Align Technology, Inc.
Sindhura Gaddamanugu
Sr. Regulatory Affairs Specialist II
2820 Orchard Parkway
San Jose, California 95134

Re: K232887
Trade/Device Name: Invisalign Palatal Expander System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: September 18, 2023
Received: September 18, 2023

Dear Sindhura Gaddamanugu:

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,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
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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)*
K232887

Device Name
Invisalign Palatal Expander System

Indications for Use *(Describe)*
The Invisalign Palatal Expander System is indicated for the orthodontic treatment of malocclusion. The system is used for rapid expansion and subsequent holding of skeletal and/or dental narrow maxilla (upper jaw, dental arch and tooth, palate) with primary, mixed, or permanent dentition during orthodontic or orthopedic treatment in children or adolescents. In adults, it is to be used in conjunction with surgery or other interventions when necessary.

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 - K232887

Align Technology's Invisalign System Palatal Expander (IPE) System

General Information

510(k) Sponsor	Align Technology, Inc.
Address	2820 Orchard Parkway San Jose, CA 95134
FDA Registration Number	2953749
Contact Person	Sindhura Gaddamanugu Sr. Regulatory Affairs Specialist II, Regulatory Affairs Align Technology, Inc. cc: Shweta Daga Director, Regulatory Affairs Align Technology Inc.
Contact Information	Email: sgaddamanugu@aligntech.com Phone: +1 408-470-1000 Fax: +1408-470-1010
Date Prepared	September 18, 2023

Name of Modified Device and Name/Address of Sponsor

Name of Device	Invisalign Palatal Expander (IPE) System
Name/Address of Sponsor	Align Technology, Inc. 2820 Orchard Parkway, San Jose, CA 95134
Trade/Proprietary Name	Invisalign Palatal Expander (IPE) System
Common Name	Palatal Expander, Sequential
Classification Name	Orthodontic Plastic Bracket
Regulation Number	21 CFR 872.5470
Product Code	NXC
Regulatory Class	II

Primary 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

Secondary Predicate Device

Name of Device	Dentaurum Expansion Screws
Name/Address of Sponsor	Dentauraum, Inc.
Trade/Proprietary Name	Dentaurum Expansion Screws
Common Name	Retainer, Screw Expansion, Orthodontic
Classification Name	Orthodontic appliance and accessories
Regulation Number	21 CFR 872.5410
Product Code	DYJ
Regulatory Class	I

Purpose of the Traditional 510(k) Notice

The purpose of this Traditional 510(k) notice is to request clearance for the Subject device, the Invisalign Palatal Expander (IPE) System. Additionally, this Traditional 510(k) introduces the proprietary, 3D Shape generation software, and labeling documentation associated with the Invisalign Palatal Expander System.

Intended Use/Indications For Use

The intended use of the Subject device is as follows:

The Invisalign Palatal Expander System is intended for use in the treatment of dental and/or skeletal malocclusion in primary, mixed or permanent dentition.

The Indications for Use of the subject device is as follows:

The Invisalign Palatal Expander System is indicated for the orthodontic treatment of malocclusion. The system is used for rapid expansion and subsequent holding of skeletal and/or dental narrow maxilla (upper jaw, dental arch and teeth, palate) with primary, mixed, or permanent dentition during orthodontic or orthopedic treatment in children or adolescents. In adults, it is to be used in conjunction with surgery or other interventions when necessary.

The general purpose of the subject device and the primary predicate, i.e. Invisalign System and the secondary predicate device (Dentaurum Expansion Screws) is the treatment of malocclusion and the subject device's intended use falls within the intended use of the predicate devices. The subject device and the primary predicate device are indicated for the treatment of malocclusion. Additionally, the subject device and the secondary predicate device are used for rapid expansion of narrow maxilla. While the Indication for Use is similar, both the subject and primary predicate device have the same intended use that is used in the treatment of dental or skeletal malocclusion in primary, mixed or permanent dentition.

Device Description

The subject device, Invisalign Palatal Expander (IPE) System (hereafter referred to as the IPE System) is a modification to the legally marketed multiple predicate devices, Invisalign System (Class II; Product Code: NXC; K220287) as Primary and Dentaurum Expansion Screws/Hyrax Expander – Hyrax ® and Hyrax neo® (Class I, Product Code: DYJ, K935154) as Secondary.

The IPE System consists of the Invisalign Palatal Expanders, Invisalign Palatal Holders, the Attachment Template and the proprietary 3D Shape generation software.

Invisalign Palatal Expanders are a staged series of removable orthodontic devices designed to expand the patient's skeletal and/or dental narrow maxilla (upper jaw, dental arch, teeth and palate) in small increments to an optimal position determined by the doctor. Once the desired clinical outcome of the expansion phase has been achieved, patients progress to the holding phase.

The Invisalign Palatal Holder is a copy of the last stage of the expansion phase designed to hold the maxilla post active expansion, to allow the maxilla to stabilize before the patient progresses to the next phase of treatment (retention, phase 2 or other treatment).

The proprietary Align internal personnel-facing 3D software enables Align's computer-aided design (CAD) designers to generate the shape and quantity/stages of the device. Using this software, CAD designers create digital files for the incremental stages of the doctor-prescribed expansion amount and the design and quantity of holders per the prescribed holding duration. Each device in the series is fabricated via additive manufacturing (3D printing).

The Attachment Template (also a component of the primary predicate device, the Invisalign System) enables correct placement and bonding of attachments made of dental composite (material provided by doctor) to the tooth surface for IPE engagement and retention.

Comparison with Predicate Devices

In accordance with 21 CFR 807.92(a)(6) a summary of the technological characteristics' comparison of the proposed subject device to the predicate devices is provided below.

Technological Characteristics Comparison with the Predicate Devices

The IPE System provides an additional method for palate expansion during malocclusion treatment as achieved with the primary and secondary predicate devices. The technological differences are limited to the material, additive manufacturing, and the 3D Software used to deliver a patient-matched device to meet its proposed intended use.

Table 7-1: Substantial Equivalency Overview

	Subject Device **Invisalign Palatal Expander System**	**Primary Predicate Device** **Invisalign System (K220287)**	**Secondary Predicate Device** **Dentaurum Expansion Screws (K935154)**	**Substantial Equivalency**
Indication for Use, User Population				
Intended Use	The Invisalign Palatal Expander System is intended for use in the treatment of dental and/or skeletal malocclusion in primary, mixed or permanent dentition.	The Invisalign System is intended for use in the treatment of dental or skeletal malocclusion in primary, mixed and permanent dentition.	The Expansion Screw is intended for use in the treatment for palatal expansion in all dentition types.	**Same** as primary predicate device **Similar** to secondary predicate device The subject device's intended use falls within the intended use of the secondary predicate device.
Indications for Use	The Invisalign Palatal Expander System is indicated for the orthodontic treatment of malocclusion. The system is used for rapid expansion and subsequent holding of skeletal and/or dental narrow maxilla (upper jaw, palate, dental arch and teeth) with primary, mixed, or permanent dentition during orthodontic or orthopedic treatment in children or adolescents. In adults, to be used in conjunction with surgery or other interventions when necessary.	The Invisalign System is indicated for the orthodontic treatment of malocclusion.	The device is indicated for case of transverse under-development of the upper jaw.	**Similar** to primary predicate device **Same** as the secondary predicate device The subject device and the primary predicate device have similar Indication for Use and both are indicated for the treatment of malocclusion. Both the subject device and the secondary predicate device have the same indication for use to expand the narrow maxilla/upper jaw.
Patient Population	Children, Adolescents and Adults	Children, Adolescents and Adults	All patients for whom a fixed appliance with an expansion screw can be placed as part of orthodontic treatment.	**Same** as primary predicate device **Similar** to secondary predicate device The subject device patient

	Subject Device **Invisalign Palatal Expander System**	**Primary Predicate Device** **Invisalign System (K220287)**	**Secondary Predicate Device** **Dentaurum Expansion Screws (K935154)**	**Substantial Equivalency**
				population is the same as the primary predicate device and the population is a subset of secondary predicate device patient population.
Use Location	Dental intraoral devices.	Dental intraoral devices.	Dental intraoral devices.	**Same** as primary and secondary predicate devices
OTC or Prescription (Rx) Device	Rx only	Rx only	Rx only	**Same** as primary and secondary predicate devices
Principal of Operation				
Principle of Operation	**Expanders:** Sequential expanders apply continuous outward pressure/force to the maxilla.	**Aligners:** Sequential aligners apply continuous gentle force to the teeth and/or position mandible forward.	Hyrax has an expansion screw suspended above the palatal vault/gingiva. A key is used to turn the expansion screws (quarter turn - 90 degrees rotation) on a specified schedule per the doctor's discretion, and this keeps the pressure on both halves of the jawbone causing them to widen and move apart. The number of quarter turns per day is instructed by the doctor to the patient and/or parent/supervising adult per the treatment plan for rapid or slow expansion.	**Similar** to primary and secondary predicate devices. Subject device operates same as primary predicate device in the context of removability, exerting continuous force, and sequential devices. Subject device and secondary predicate operate similarly regarding separating the mid-palatal suture and movement of maxillary halves. Subject device and secondary predicate device operate similarly by exerting continuous force.

	Subject Device **Invisalign Palatal Expander System**	**Primary Predicate Device** **Invisalign System (K220287)**	**Secondary Predicate Device** **Dentaurum Expansion Screws (K935154)**	**Substantial Equivalency**
	Holders: The palatal holder is a copy of last stage of the expansion phase.	**Retainers:** The retainers are a copy of the last stage of the aligners. Note: Invisalign Retainers are not part of the primary predicate device Invisalign System (K220287) as they are classified as a Class I under 21CFR872.5525.	The expansion screw-based device should remain in the mouth after active expansion without turning the screw for approximately 2 – 3 months for stabilization purposes and to avoid relapse.	**Similar** to the primary and secondary predicate devices Subject device has the same principle of operation of maintaining and preventing movement using passive devices as both predicate devices.
Technological Characterization				
Software	Produces 3D-model file of the IPE devices based on the digital scan and doctor/dental practitioner's prescription. 3D Software of the subject device is an internal Align facing only shape generation software which includes software algorithms that are used to determine the shape and calculate the quantity of devices required per the doctor prescribed expansion distance and holding duration.	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.	Not Applicable	**Similar** to the primary predicate. The 3D software used in the subject and predicate devices are both used for treatment planning and designing the shape of the device. The subject device utilized a simplified version of 3D software based on the purpose and design of the device.
Materials	Thermoplastic polyamide	Thermoplastic polymer	The screws are made of stainless steel (DIN 1.4301,	**Similar** to the primary predicate device.

	Subject Device **Invisalign Palatal Expander System**	**Primary Predicate Device** **Invisalign System (K220287)**	**Secondary Predicate Device** **Dentaurum Expansion Screws (K935154)**	**Substantial Equivalency**
			DIN 1.4305 and DIN 1.4310).	
Performance Testing				
Durability	Durability was tested to verify the performance of the IPE device. All IPE devices maintained the engagement on attachments, without deformation, cracks, chips or breaks.	No new durability testing was required with the primary predicate device pre-market notification (K220287). Durability testing was performed on previously cleared Invisalign System and testing results met all acceptance criteria.	Unknown	**Same** as primary predicate device
Stiffness/ Force system	The subject device was tested to verify that the device is structurally stiff and can deliver the required force in the lateral direction on the posterior teeth. The test results met the acceptance criteria and performed as intended.	No new force system testing was required with the primary predicate device pre-market notification (K220287). Force mechanical verification testing demonstrated with previously cleared Invisalign System provides adequate force systems on the dentition for its intended use.	The mechanical behavior (stiffness/force) of Hyrax was used as one of the acceptance criteria for the subject device bench testing.	**Similar** to Primary Predicate device **Same** as secondary predicate device
Packaging	The subject device was tested to validate that the packaging can protect the System from exposure to all relevant shipping and handling scenarios. The testing confirmed that the product integrity was maintained during	No new packaging validation testing was required with the primary predicate device pre-market notification (K220287). The Packaging validation testing on previously	Unknown	**Similar** to Primary Predicate device Both the subject and primary predicate devices use the same primary packaging, and packaging testing on the subject device confirmed

	Subject Device Invisalign Palatal Expander System	**Primary Predicate Device Invisalign System (K220287)**	**Secondary Predicate Device Dentaurum Expansion Screws (K935154)**	**Substantial Equivalency**
	shipping and handling scenarios.	cleared Invisalign System demonstrated that the device integrity was maintained during the various shipping and handling scenarios.		that device integrity is maintained during all relevant shipping and handling scenarios
Retention	The subject device was tested to verify that the device can retain engagement with attachments on posterior teeth while the device is under compression during an active expansion and holding period. The test results met the acceptance criteria and performed as intended.	No new testing was required with the primary predicate device pre-market notification (K220287). Retention testing performed on previously cleared Invisalign System demonstrated that the device performed as intended.	Unknown	**Similar** to Primary Predicate device
Insertion and Removal Force	The Insertion and Removal Force test was conducted to verify that the forces required to insert and remove device are significantly less than the bond force of the attachment on the tooth.	No force system testing was required with the primary predicate device pre-market notification (K220287). The testing performed on previously cleared Invisalign System demonstrated that the device performed as intended.	Unknown	**Similar** to Primary Predicate device
Human Factors & Usability	Human factors & Usability testing was conducted on the subject device to validate that it is	No human factors & usability validation testing was required for the primary	Unknown	**Similar** to Primary Predicate device Based on available data,

	Subject Device **Invisalign Palatal Expander System**	**Primary Predicate Device** **Invisalign System (K220287)**	**Secondary Predicate Device** **Dentaurum Expansion Screws (K935154)**	**Substantial Equivalency**
	adequately designed for its intended users, uses and use environments	predicate device pre-market notification (K220287). Human Factors & Usability validation on previously cleared Invisalign System has been found to be adequately designed for the intended users, uses, and use environments.		both the subject device and primary predicate device perform as intended and additional device modifications to the user interface are not needed and would not further reduce risk.
Clinical Performance/ Study				
Clinical Testing	Not Applicable. An early feasibility study was conducted which concluded that desired active expansion of the upper jaw width was observed in all the subjects. There were no unanticipated or serious adverse events reported from this study. Additionally, real-world data was also analyzed from commercially available product.	Not Applicable	Not Applicable	**Similar** to primary predicate and secondary predicate devices. The subject device is a Class II medical device and clinical testing was not warranted to support substantial equivalency with the primary and secondary predicate devices.

Performance Data

The IPE System underwent a complete set of functional and performance testing, including, durability, expander fatigue/insertion & removal, bioburden, and packaging validation testing. Clinical performance of the IPE System was also evaluated in an early feasibility study and real-world data post-market study. Based on the performance testing outcomes, the subject device,

the IPE System is substantially equivalent to its predicates and there are no new risks from the differences between the subject device and the predicate devices.

Biocompatibility

Biocompatibility testing for the proposed IPE System was completed 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 IPE System does not pose any significant biologicals risks and is considered safe for its intended use in the intra-oral cavity.

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 orthodontic software component of the subject device.

Substantial Equivalence

The subject device is similar to its predicate devices in that it has:

- intended use, same as primary predicate device and similar to secondary predicate device;
- indications for use, similar to primary predicate device and same as secondary predicate device;
- principles of operation, similar to both predicate devices; and
- technological characteristics, similar to primary predicate device

The differences in the indications for use, principles of operation and technological characteristics between the subject device and its predicate devices do not raise different questions of safety or efficacy. Therefore, the subject device is found to be substantially equivalent to the legally marketed primary predicate device, Invisalign System (K220287) and secondary predicate device, Dentaurum Expansion Screws.

Conclusion

Align Technology's Invisalign Palatal Expander (IPE) System has the same intended use and similar indications for use as the previously cleared primary predicate, Invisalign System (K220287). The IPE System has similar intended use and same indications for use as the secondary predicate device Dentaurum Expansion Screws. The difference in principles of operation and technological characteristics between the subject device and the predicate devices were evaluated using standard test methods and do not raise new issues of safety or effectiveness. Performance data (bench and clinical) and biocompatibility testing demonstrate that the subject device is as safe and effective as both predicate devices. Thus, the Invisalign Palatal Expander (IPE) System is substantially equivalent to both predicate devices.