October 23, 2025

Align Technology, Inc
Ahanitha Ashok
Principal Regulatory Affairs Specialist
2820 Orchard Parkway
San Jose, California 95134

Re: K252931
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, PNN
Dated: October 15, 2025
Received: October 22, 2025

Dear Ahanitha Ashok:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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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)*
K252931

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 teeth, palate) with primary, mixed, or permanent dentition and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K252931

510(k) Summary

Prepared on: 2025-10-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Align Technology, Inc
Applicant Address	2820 Orchard Parkway San Jose CA 95134 United States
Applicant Contact Telephone	(925) 596 0355
Applicant Contact	Ms. Ahanitha Ashok
Applicant Contact Email	aashok@aligntech.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Invisalign Palatal Expander System
Common Name	Orthodontic plastic bracket
Classification Name	Aligner, Sequential
Regulation Number	872.5470
Product Code(s)	NXC, PNN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K232887	Invisalign Palatal Expander System	NXC, PNN
K252380	Invisalign System	NXC, PNN

Device Description Summary

21 CFR 807.92(a)(4)

The Invisalign® Palatal Expander (IPE) System (subject device) consists of a series of doctor prescribed, additive manufactured (3D Printed), removable orthodontic appliances (Invisalign® Palatal Expanders and Invisalign® Palatal Holders), and proprietary Align internal personnel facing shape generating 3D Orthodontic Software. The IPE 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 (primary and permanent), or permanent dentition during orthodontic or orthopedic treatment in children or adolescents. In adults, the IPE System is to be used in conjunction with surgery or other interventions when necessary. The proprietary 3D Orthodontic Software creates digital files for IPE System to be manufactured using digital data from the doctor/dental practitioner's prescription and patient scans. This submission adds an optional engagement feature to the existing Invisalign Palatal Expander System. Engagement features support the usage of commercially available orthodontic accessories such as elastics per the doctor's treatment plan for the treatment of malocclusion.

This submission adds an optional engagement feature to the existing Invisalign® Palatal Expander System (K232887). The proposed addition of engagement feature to IPE System is similar to the reference device, Invisalign System (K252380). Engagement features are designed to provide an anchor point to support the usage of commercially available orthodontic accessories such as elastics per the doctor's treatment plan for the treatment of malocclusion without altering the principle of operation of the device. The engagement features can be either forward facing or backward facing per the doctor's treatment plan. The IPE System with engagement features are additive manufactured using the same material as the predicate device (proprietary thermoplastic polyamide) and use the same manufacturing process as the predicate device.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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 and 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The intended use and indications for use are the same as predicate device, K232887.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device and predicate device have the following similarities:
- Same Intended Use
- Same Indications for Use
- Same principles of operation
- Same material, and product performance
- Similar technological characteristics

The difference between the subject device and predicate device is limited to the technological characteristics. The design of the subject device has been modified to add engagement features to support the usage of commercially available orthodontic accessories such as elastics per the doctor's treatment plan for the treatment of malocclusion without altering the principle of operation of the device. The engagement features are manufactured using the same material and same manufacturing process as the predicate device. The proposed engagement features technological characteristics are similar to the reference device, Invisalign System (K252380). The verification and validation testing results demonstrated that the technological difference of the addition of engagement features does not raise any safety and effectiveness questions, and the subject device is substantially equivalent to the predicate device, K232887.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The subject device, Invisalign® Palatal Expander System underwent a complete set of functional and performance testing, including stiffness, retention, and durability testing with additional orthodontic accessories, using similar test methods as the predicate and reference device. All testing passed acceptance criteria and demonstrated the device modification does not affect the safety and effectiveness of Invisalign® Palatal Expander System. The results conclude that the difference in technological characteristics between the subject device and its predicate devices does not raise different questions of safety or effectiveness. Thus, the subject device is found to be substantially equivalent to the legally marketed predicate device, Invisalign Palatal Expander System (K232887).