October 9, 2025

Align Technology, Inc.
Niya Su
Sr. Manager, Regulatory Affairs
2820 Orchard Parkway
San Jose, CA 95134

Re: K252870
Trade/Device Name: Invisalign Specifix Attachment System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC, DYT
Dated: September 9, 2025
Received: September 9, 2025

Dear Niya Su:

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
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
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Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252870

Please provide the device trade name(s).

Invisalign Specifix Attachment System

Please provide your Indications for Use below.

Invisalign Specifix Attachment System is a directly fabricated accessory indicated to bond attachments and/or engagement features to apply force for tooth movement during orthodontic treatment of malocclusion, and/or for retention of Align orthodontic appliances.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K252870

510(k) Summary

Prepared on: 2025-10-07

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	206-779-7758
Applicant Contact	Ms. Niya Su
Applicant Contact Email	n.su@aligntech.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Invisalign Specifix Attachment System
Common Name	Orthodontic plastic bracket
Classification Name	Aligner, Sequential
Regulation Number	872.5470
Product Code(s)	NXC, DYT

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222894	Invisalign System, Pre-formed Attachment System	NXC

Device Description Summary

21 CFR 807.92(a)(4)

Align Technology, Inc. is submitting this Special 510(k) to modify Align's Invisalign Pre-Formed Attachment System (PFA) cleared in 510 (k) K222894. The brand name of subject (modified) device is Invisalign Specifix Attachment System.
Invisalign Specifix Attachment System is a doctor prescribed 3D-printed device intended to bond 3D-printed attachments and/or engagement features to the patient's teeth. Invisalign Specifix attachments apply force for tooth movement along with Invisalign System aligner during the orthodontic treatment of malocclusion, and/or supports retention of Align orthodontic appliances. The engagement features are intended to engage with commercially available orthodontic elastics and ligatures. Invisalign Specifix Attachment System is designed based on the doctor/dental practitioner's prescription and patient's' anatomical tooth surface. The dentition-matched Invisalign Specifix Attachment System allows dental practitioner to seat the device on the patient's unique dentition, and facilitates placement of attachments and/or engagement features during bonding and are removable post bonding.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Invisalign Specifix Attachment System is a directly fabricated accessory indicated to bond attachments and/or engagement features to apply force for tooth movement during orthodontic treatment of malocclusion, and/or for retention of Align orthodontic appliances.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the subject device is different than the predicate Invisalign Pre-Formed Attachment System with the addition of engagement features and retention of additional Align orthodontic appliance. The addition of engagement feature does not constitute a new intended use of the device, which is to apply force for tooth movement during treatment of malocclusion.
The predicate device provides retention of Invisalign System aligner. The subject device provides retention of additional Align

orthodontic appliance. This change does not affect the intended use of the device which provides retention of orthodontic appliance.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device and predicate device have the following similarities:
• Same Intended Use and similar Indications for Use;
• Same principles of operation;
• Similar technological characteristics and functional characteristics.

The subject device and predicate device have the following differences:
• Subject device has different material than the predicate device;
• Subject device has engagement features to engage with orthodontic accessories, such as elastics and ligatures;
• Subject device can provide retention for Align orthodontic appliances, whereas predicate device provides retention for Invisalign System aligner only;
• Subject device has modified packaging to enhance package integrity during transportation. The number of devices in the package is not changed.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The subject device, Invisalign Specifix Attachment System, was evaluated through a complete set of biocompatibility and bench testing including flexural strength, wear by toothbrushing, water sorption and solubility, shear bond strength, force system, packaging validation, stability, volume precision, button retention and fatigue test, button shear bond force, and retention force test with additional Align orthodontic appliance. The testing performed was in alignment with the recommendations in the FDA guidances titled "Technical Considerations for Additive Manufactured Medical Devices" and "Denture Base Resins - Performance Criteria for Safety and Performance Based Pathway." All testing passed acceptance criteria and demonstrated that the subject/modified device is substantially equivalent to the predicate device.