



September 25, 2026

Align Technology, Inc.
Sindhura Gaddamanugu
Principal Regulatory Affairs Specialist
2820 Orchard Pkwy.
San Jose, California 95134

Re: K262196

Trade/Device Name: Invisalign System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN, NXC
Dated: June 29, 2026
Received: June 29, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Office of Product Evaluation and Quality
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.

K262196

?

Please provide the device trade name(s).

?

Invisalign System

Please provide your Indications for Use below.

?

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.

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

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☒ Children (2 years old to < 12 years old)

☒ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

?

Align Technology

Invisalign System Traditional 510(k)

510(k) Summary - K262196

510(k) Summary

Contact Details 21 CFR 807.92(a)(1)

Applicant Name	Align Technology, Inc.
Applicant Address	2820 Orchard Parkway, San Jose, CA 95134
Applicant Contact Phone	407-922-3884
Applicant Contact	Ms. Sindhura Gaddamanugu
Applicant Contact Email	sgaddamanugu@aligntech.com
Date Prepared	June 25, 2026

Device Name 21 CFR 807.92(a)(2)

Name of Device	Invisalign System
Common Name	Orthodontic Plastic Bracket
Classification Name	Aligner, Sequential
Regulation Number	21 CFR 872.5470
Product Codes	NXC, PNN

Legally Marketed Predicate Devices 21 CFR 807.92(a)(3)

Predicate Device	K252380
Predicate Trade Name (Primary Predicate is listed first)	Invisalign System
Product Codes	NXC, PNN

Device Description Summary 21 CFR 807.92(a)(4)

The subject device, Invisalign System, is a proposed modification to add an optional AI-enabled prediction service to the predicate device, Invisalign System (K252380). The Invisalign System consists of removable orthodontic appliances (aligners) and proprietary 3D treatment planning software. This submission introduces the integration of an optional AI-enabled prediction service to the backend 3D treatment planning software to support Invisalign treatment planning by optimization of aligner activation design.

Like the predicate device, the Invisalign system consists of a series of doctor prescribed, customized, thin, clear plastic aligners that gently move the patient's teeth in small increments

ALIGN CONFIDENTIAL

Page 1 of 3

from their original state to a more optimal, treated state to address malocclusion. The system is used in patients with primary, mixed and permanent dentition. There are no changes to the end-to-end user workflow and conditions of use of the Invisalign System. The subject device treatment prescription remains the same as the predicate device for eligible cases; no new inputs are required.

As per current Invisalign treatment planning, the proprietary 3D software integrated with the AI-enabled prediction service generates the treatment plan which is reviewed and approved by the doctor prior to manufacturing. There is no direct user interaction with the AI-enabled functionality of the Invisalign System. The AI model used in the prediction service is static and non-adaptive.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The intended use and the indications for use are the same as the predicate device (K252380)

Technological Comparison

21 CFR 807.92(a)(6)

Invisalign System subject device and the cleared predicate Invisalign System (K252380) are similar in that they have:

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

The proposed modification is limited to the principle of operation and technological characteristics of the backend components of the proprietary treatment planning software. There is no change to the intended use/indications for use, the principle of operation or design of the Invisalign System Aligners and the end-to-end user workflow of the Invisalign System.

Non-Clinical and/or Clinical Tests Summary & Conclusions **21 CFR 807.92(b)**

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

The subject device underwent performance validation to support the functional and clinical performance of the Invisalign System with the optional AI-enabled prediction service. The data set used for performance validation is representative of the population for whom the optional AI-enabled prediction features are intended. Potential bias and data generalizability across varied subgroups (including geographic, demographic, and clinical severity) were evaluated.

Primary endpoint analysis demonstrated pre-specified acceptance criteria were met. Detailed information including subgroup analyses is provided in the premarket notification.

The non-clinical and clinical performance testing results demonstrated that the subject/modified device is substantially equivalent to the predicate device and does not raise any new questions of safety and effectiveness.