August 29, 2025

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

Re: K252380
Trade/Device Name: Invisalign System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC, PNN
Dated: July 30, 2025
Received: July 30, 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,




For Michael E. Adjodha, M.ChE., 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. | K252380 |

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

510(k) #: K252380

# 510(k) Summary

Prepared on: 2025-07-30

## 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 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 |
|---|---|---|
| K241412 | Invisalign System | NXC |

## Device Description Summary

21 CFR 807.92(a)(4)

The subject device Invisalign® System is a proposed modification to add integrated button, an optional feature into the predicate device, Invisalign System (K241412). The Invisalign® System consists of removable orthodontic appliances (aligners) and proprietary 3D treatment planning software. This submission adds an optional integrated button to aligners which is similar to the predicate device's precision cut feature that allows doctors to add orthodontic accessories such as elastics during treatment. The 3D treatment planning software allows the visualization and button placement on the aligners. The doctor still approves the treatment plan prior manufacturing, which is the same as that in the predicate.

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 from their original state to a more optimal, treated state to address malocclusion. The optional MAF positions patients jaw forward to address skeletal malocclusion. The system is used in patients with primary, mixed, and permanent dentition. There are no changes introduced to the user workflow other than the addition of optional integrated button feature.

## 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 indications for use are the same as predicate device, K241412.

## Technological Comparison 21 CFR 807.92(a)(6)

The subject device has similar technological characteristics as the predicate device. The design of the subject device has been modified to add button. The prescribed button feature is an additional optional feature to provide support to orthodontic accessories such as elastics to treat Class II and Class III malocclusion. The buttons are integrated onto the aligners. The proposed modification does not raise any safety and effectiveness concerns as the mechanism of action for the treatment of malocclusion is the same as the predicate device, K241412.

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

The subject device, Invisalign® System underwent a complete set of functional and performance testing, including durability, shear bond, retention, and bicompatibility testing. All testing passed acceptance criteria and demonstrated the device modification does not affect the safety and effectiveness of Invisalign® System and does not raise any new questions of safety and effectiveness.