



January 7, 2026

Beame Medical Technology (Shenzhen) Limited
% Riley Chen
RA Specialist
Feiyang Drug & Medical Consulting Technical Service Group
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Shenzhen, Guangdong 518052
CHINA

Re: K251454
Trade/Device Name: Clear Aligner (SCF-3348)
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: December 15, 2025
Received: December 15, 2025

Dear Riley Chen:

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

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K251454

Device Name
Clear Aligner (SCF-3348)

Indications for Use (Describe)

Clear Aligner is indicated for use in the alignment of permanent teeth (i.e., all second molars) through orthodontic treatment of misalignment and malocclusion.

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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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

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Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Clear Aligner (SCF-3348)
Common Name	Orthodontic plastic bracket
Classification Name	Aligner, Sequential
Regulation Number	872.5470
Product Code(s)	NXC

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233356	Illusion Aligner Pro	NXC
K230237	Dental Braces (Model: HK-Y-0.4, HK-Y-0.45, HK-Y-0.63, HK-Y-0.7, HK-Y-ST-0.76, HK-Y-CF-0.76, HK-Y-0.9, HK-Y-1.0, HK-Y-2.0)	KMY

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The first step is to obtain the dimensions and details of the patient's upper and lower dentition from the prescribing clinician who takes impressions or scans of the patient's teeth and sends them to the lab. The scanned data (oral scans or printed models) are imported into specialized dental software for treatment planning.

The second step is to send the treatment plan to the dentist for review and approval, then print the 3D models of the treatment plan for

use in step 3 (thermoforming). In the second step, we utilize a software application to plan the treatment by creating a series of sequential models that gradually position the teeth into their final desired position. A 3D printer is used to create the corresponding molds needed for this series of sequential models, and hot-press the molds into the corresponding aligners. The final step is to thermoform the printed mold through a plastic sheet. This process is done using a standard thermoforming equipment and the appropriate material as outlined in this submission. The thermoformed aligners are then sent back to the dentist for distribution to the patient in sequential stages and that the dentist checks the aligners for fit and function and monitors the treatment from the first aligner until treatment is completed. Specialized orthodontic CAD/CAM software will be used to develop the treatment plans and to produce standard 3D printer files that will facilitate the manufacturing of each sequential aligner in the treatment plan. The software application used for the manufacturing validation in this submission is the 3shape Ortho System™.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

Clear Aligner is indicated for use in the alignment of permanent teeth (i.e., all second molars) through orthodontic treatment of misalignment and malocclusion.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The Clear Aligner has the same indications for use as the predicate device, they both are indicated for use in the alignment of permanent teeth (i.e., all second molars) through orthodontic treatment of misalignment and malocclusion.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The Clear Aligner is identical to the predicate device in the following:

- a) Indications for use
- b) Materials: Thermoplastic polyurethane (TPU)
- c) Mode of action: Continuous gentle force applied to teeth to achieve movement.
- d) Manufacturing method: Thermoforming

Both the subject device and the predicate device (K233356) are custom-made aligners manufactured using the same material — thermoplastic polyurethane — and using the same manufacturing method of thermoforming. Consequently, the subject device aligns with the legally marketed predicate device in terms of material composition, processing techniques, and overall indications for use, thereby supporting substantial equivalence.

Furthermore, the raw materials for the subject device are sourced directly from the reference device (K230237). According to the production process of Clear Aligner, manufacturing involves first using software to print molds via 3D-printing technology based on the treatment plan. Subsequently, a thermoforming machine is employed to shape the TPU material into aligners on these molds. This processing technique only changes the physical shape of the material to fit the patient's dental mold without affecting its chemical properties. No colorants/dyes or additives are introduced during the process, thus will not affect and/or change the biocompatibility performance of the raw material, thereby, the biocompatibility test reports of the reference device can be used to support substantial equivalence.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Non-clinical tests have been conducted to verify that the Clear Aligner meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate devices.

The testing results demonstrate that the subject device complies with the following standards:

- a. ISO 10993-1:2018, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- b. ISO 7405:2018, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
- c. ISO 10993-5:2009, Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
- d. ISO 10993-10:2021, Biological evaluation of medical devices — Part 10: Tests for skin sensitization
- e. ISO 10993-23:2021, Biological evaluation of medical devices — Part 23: Tests for irritation
- f. ISO 10993-3:2014, Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- g. ISO 10993-11:2017, Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

Performance Testing

Manufacturing validation testing was conducted to validate the manufacturing process of the final product. The test met the pre-established acceptance criteria, and the test results showed that the manufacturing process of the subject aligner achieved its intended use, and was substantially equivalent to the predicate device.

The clinical test is not applicable, there's no clinical data.

Based on the above analysis and tests, the subject device is substantially equivalent to the predicate device.