December 12, 2024

Geniova Technologies Sociedad Limitada
℅ Juan Tezak
Consultant
Compliance4Devices
118 W Prive Cr.
Delray Beach, Florida 33445

Re: K233152
Trade/Device Name: GENIOVA aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: September 27, 2023
Received: September 27, 2023

Dear Juan Tezak:

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233152

Device Name

GENIOVA Aligners

Indications for Use *(Describe)*

GENIOVA Aligners are indicated for use in the alignment of permanent teeth (i.e., all second molars) through orthodontic treatment of misalignment and malocclusion. The aligners guide teeth to their final position by way of continuous gentle forces.

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) Summary

GENIOVA Aligners
K233152
March, 2024

ADMINISTRATIVE INFORMATION

Applicant

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DEVICE AND CLASSIFICATION NAME

Device Trade Name:	GENIOVA Aligners
Common Name:	Orthodontic plastic bracket.
Device Classification:	Class II, 21 CFR 872.5470
Classification Panel:	Dental
Product Code:	NXC – Orthodontic plastic bracket

Predicate Device Information

Predicate Device:	K202792 – BRIUS Clear Aligners
Reference Device:	K180941 – Ortho System
	K062828 – Essix ACE Plastic

Intended Use

GENIOVA Aligners are indicated for use in the alignment of permanent teeth (i.e., all second molars) through orthodontic treatment of misalignment and malocclusion. The aligners guide teeth to their final position by way of continuous gentle forces.

Device Description

GENIOVA aligners are thermoformed plastic aligners designed to be used in sequence to facilitate the movement of teeth to the desired final position. Sequential aligners introduce incremental movements that move teeth by a gentle continuous force. Aligners should be worn 20 to 22 hours a day and should be removed for eating and cleaning.

GENIOVA aligners are designed based on traditional mold impression or digital scans of the patient's dentition submitted by a dental health professional (e.g., a dentist or orthodontist). From the scan, specialized orthodontic CAD/CAM software is used to develop the treatment plans, which consist of sequential dental models in which the teeth are gradually realigned at each step. For these 510(k) applications, the Ortho system from 3Shape A/S (K180941) will be used.

(K180941) from 3Shape A/S. Ortho System is approved for use in orthodontic model management, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options. The specialized orthodontic treatment planning software has 510k clearance for intended use under FDA Classification Product Code PNN, regulation 872.5470.

Once the treatment plan is reviewed and approved by a dental health professional, each 3D model from the treatment plan is manufactured. The aligner trays are then manufactured by thermoforming a dental thermoplastic sheet over each model. The Essix thermoplastic material used for BRIUS Clear Aligners has 510(k) clearance (K062828) for use as an aligner material; the 510(k) holder (of the material) conducted the physical properties testing for the material.

The aligner trays are then delivered to the patient by the prescribing dental health professional. This dental health professional then monitors the patient’s treatment from the placement of the first aligner to the delivery of the final aligner and completion of treatment. The aligners are held in place by pressure and can be removed by the patient at any time.

Equivalence to Marketed Device

GENIOVA Aligners are functionally equivalent to the following predicate device: BRIUS Clear Aligners (K202792). The following table demonstrates the functional specifications of GENIOVA Aligners are substantially equivalent to the predicate devices.

Table 1. Comparison with predicate device for Summary

Specification	Subject Device: GENIOVA Aligners	Predicate Device: BRIUS Clear Aligners (K202792)	Comparison Result
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	Same
Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Same
Product Code	NXC	NXC	Same
Classification	Class II	Class II	Same

Specification	Subject Device: GENIOVA Aligners	Predicate Device: BRIUS Clear Aligners (K202792)	Comparison Result
OTC or Rx	Rx	Rx	Same
Material	Essix Thermoplastic (K062828)	Essix Thermoplastic (K062828)	Same
Material Properties	Acceptable material properties established for use as an aligner.	Acceptable material properties established for use as an aligner.	Same
Biocompatible	Yes	Yes	Same
Sterile	Non-sterile	Non-sterile	Same
Device Description	Sequential thermoformed plastic aligners	Sequential thermoformed plastic aligners	Same
Patient Removable?	Yes	Yes	Same
Indication for Use	GENIOVA Aligners are indicated for use in the alignment of permanent teeth (i.e., all second molars) through orthodontic treatment of misalignment and malocclusion. The aligners guide teeth to their final position by way of continuous gentle forces.	BRIUS Clear Aligners are indicated for use in the alignment of permanent teeth (i.e., all second molars) through orthodontic treatment of misalignment and malocclusion. The aligners guide teeth to their final position by way of continuous gentle forces.	Same
Mode of Action	Continuous gentle force applied to teeth following the prescribed and approved treatment plan to achieve orthodontic movement	Continuous gentle force applied to teeth following the prescribed and approved treatment plan to achieve orthodontic movement	Same
Anatomy Location	Mouth; mucosal membranes	Mouth; mucosal membranes	Same
Size	Patient specific	Patient specific	Same
Manufacturing Method	Thermoforming	Thermoforming	Same
Software used to design aligners	3Shape A/S's Ortho System (K180941)	3Shape A/S's Ortho System (K180941)	Same

Based on the above comparison, the indications for use, the design, construction, and performance characteristics of the GENIOVA Aligners is similar to that of the BRIUS Clear Aligners (K202792). Thus, the GENIOVA Aligners can be considered substantially equivalent to its predicate device.

Non-Clinical Testing Summary

The use of thermoplastic materials for sequential aligners intended to treat malocclusions has been well documented in scientific literature regarding incremental tooth moving forces. However, durability testing was conducted on the aligners. Real world use was simulated to ensure that the

aligner material and manufacturing process produced aligners that were suitable for their prescribed period of use.

An internal manufacturing validation was performed to establish the dimensional accuracy of the manufacturing process for GENIOVA Aligners. The submitted intraoral scans, digital dentition models from treatment planning, 3D printed molds, and the final thermoformed aligners were all assessed quantitatively or qualitatively in the validation. Thus, each critical element in the manufacturing process was evaluated.

For the validation, digital calipers were used to perform point-to-point and critical displacement measurements, and visual inspections were performed to assess the aligner qualitatively.

Translational measurements were within 0.150 mm (150 microns) of the target input value, the predefined tolerance of the manufacturing process. There were no significant differences in the difference in the intended and measured values observed from any of the groups. This test has met the pre-established acceptance criteria to demonstrate dimensional accuracy.

The Essix thermoplastic material used for GENIOVA Aligners has 510(k) clearance (K062828) for use as an aligner material; the 510(k) holder (of the material) conducted the physical properties testing for the material. Biocompatibility testing for the aligner material, the only patient contacting material, was conducted by the 510(k) holder in accordance with International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”.

Additional cytotoxicity testing according to ISO 10993-5:2009 was performed on final manufactured GENIOVA Aligners.

Clinical Testing Summary

Clinical performance testing was not conducted.

Conclusion

Based on the information presented in these 510(k) premarket notifications the GENIOVA Aligners is considered substantially equivalent (as safe, as effective and performs as well as) to the currently marketed devices (BRIUS Clear Aligners K202792) citied in this submission. The differences noted between the GENIOVA Aligners and the predicate device do not impact safety or effectiveness based on the successfully conducted testing of the subject device.