January 22, 2021

Brius Technologies, Inc
% Jennifer Day
Regulatory Affairs Consultant
Medavice, Inc.
11218 Zest Ct. NE
Blaine, Minnesota 55449

Re: K202792
Trade/Device Name: BRIUS Clear Aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: November 20, 2020
Received: December 15, 2020

Dear Jennifer Day:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, M.ChE.
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202792

Device Name

BRIUS Clear Aligners

Indications for Use *(Describe)*

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.

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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Section 5. 510(k) Summary

510(k) SUMMARY

A summary of 510(k) information for K202792 in accordance with the requirements of 21 CFR 807.92.

Submitter: BRIUS Technologies Inc.
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Carrollton TX 75006

Company Contact Person: Ted Schwarz
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Submission Correspondent: Jennifer Day, Regulatory Affairs Consultant
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Phone: 314-809-1818
Email: jday@medavice.com

Date Prepared: September 1, 2020

Proprietary Name: BRIUS Clear Aligners

Common Name: Orthodontic plastic bracket.

Product Code: NXC – Orthodontic plastic bracket.

Device Classification: Class II, 21 CFR 872.5470

Primary Predicate Device: ClearForm Aligners (K191838)

Reference Predicates: Ortho System (K180941), Essix (K062828)

Device Description:

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

BRIUS Clear Aligners are designed from digital scans of a patient's dentition submitted by a dental health professional (e.g. dentist or orthodontist). Using the scan, specialized orthodontic CAD/CAM software will be used to develop the treatment plans that consist of sequential dental models wherein the teeth are gradually realigned with each step. For this 510(k), 3Shape A/S's Ortho System (K180941) will be used for this application. Ortho System is approved for use in the management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options. The specialized orthodontic treatment planning software has a 510k clearance for the 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 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.

Indications for Use:

The BRIUS Clear Aligners are indicated for use in the alignment of permanent dentition (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.

Comparison to Predicate Devices:

BRIUS Clear Aligners are functionally equivalent to the following predicate device: ClearForm Aligners (Motor City Lab Works, K191838 cleared March 20th, 2020). The following table demonstrates the functional specifications of BRIUS Clear Aligners are substantially equivalent to the predicate devices.

Predicate Device Comparison Table

Specification	**Subject Device:** BRIUS Clear Aligners	**Predicate Device:** ClearForm Aligners (K191838)	**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
OTC or Rx	Rx	Rx	Same
Material	Essix Thermoplastic	Essix Thermoplastic	Same
Material Properties	Acceptable material properties established for use as an aligner.	Acceptable materials 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	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.	ClearForm 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

Comparison of Indications for Use to Predicate Devices:
Based on the above comparison, the indications for use of the BRIUS Clear Aligners is similar to that of the ClearForm Aligners (K191838) as they are both 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. Thus, the BRIUS Clear Aligners can be considered substantially equivalent to its predicate device.

Comparison of Technological Characteristics to Predicate Devices:
Based on the above comparison, the design, construction, and performance characteristics of the BRIUS Clear Aligners is similar to that of the ClearForm Aligners (K191838). Thus, the BRIUS Clear Aligners can be considered substantially equivalent to its predicate device.

Non-clinical performance testing:
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 BRIUS Clear 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, independent 3rd party software and digital calipers were used to perform point-to-point and critical displacement measurements, and visual inspections were performed to assess the aligner qualitatively.

All measurements were within 0.3 mm of the target input value, the predefined tolerance of the manufacturing process. Furthermore, throughout the qualitative assessment of the aligners no performance, cosmetic, or other detectable issues were identified. This validation has met the pre-established acceptance criteria to demonstrate that the BRIUS manufacturing process yields dimensional accurate products that meet product specifications.

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. 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 BRIUS Clear Aligners.

Clinical performance testing:
Clinical performance testing was not conducted.

Conclusion:
Based on similarities in indications for use, technological characteristics, non-clinical performance testing, we believe that BRIUS Clear Aligners are substantially equivalent to the ClearForm Aligners.