October 1, 2021

BRIUS Technologies Inc
℅ Breanne Butler
Regulatory Affairs Consultant
Prime Path Medtech
1321 Upland Dr. Suite 6792
Houston, Texas 77043

Re: K212828
    Trade/Device Name: BRIUS Planner Software
    Regulation Number: 21 CFR 872.5470
    Regulation Name: Orthodontic Plastic Bracket
    Regulatory Class: Class II
    Product Code: PNN
    Dated: September 2, 2021
    Received: September 3, 2021

Dear Breanne Butler:

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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023

See PRA Statement below.

510(k) Number *(if known)*

K212828

Device Name

BRIUS Planner Software

Indications for Use *(Describe)*

BRIUS Planner is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, treatment simulation and virtual appliance design options (Patient-Specific Nitinol Wires, Sequential Aligners, Export of Models, Indirect Bonding Transfer Media) based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives.

The use of the BRIUS Planner requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.

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.

Section 5. 510(k) Summary

510(k) SUMMARY

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

Submitter:	BRIUS Technologies 2611 Westgrove Drive Carrollton TX 75006
Company Contact Person:	Mehdi Roein-Peikar
Phone:	(312) 479-1449
Email:	mehdi@brius.com
Submission Correspondent:	Breanne Butler, Regulatory Affairs Consultant
Address:	1321 Upland Dr. Suite 6792 Houston, TX 77043
Phone:	(860) 810-5594
Email:	bbutler@medavice.com
Date Prepared:	October 1, 2021
Proprietary Name:	BRIUS Planner Software
Common Name:	Orthodontic Software
Product Code:	PNN – Orthodontic Software
Device Classification:	Class II, 21 CFR 872.5470
Predicate Devices:	BRIUS Software Suite (K191720) (Primary Predicate)

Device Description:

The BRIUS Planner Software is an orthodontic appliance design and treatment simulation software. This software is used as a manufacturing software for orthodontic appliances. It is also used by professional technicians or physicians to design solutions for patients. Digital scans (3D) of a patient denture can be loaded into the software and a technician or physician can then create treatment plans for each individual patient and their needs. After approval by the patient's physician, the system can be used to fabricate dental appliances using standard stereolithographic (STL) for the design of custom shape-set nitinol appliances or clear aligners.

Indications for Use:

BRIUS Planner is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, treatment simulation and virtual appliance design options (Patient-Specific Nitinol Wires, Sequential Aligners, Export of Models, Indirect Bonding Transfer Media) based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives.

The use of the BRIUS Planner requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.

Comparison to Predicate Devices:

BRIUS Planner Software is functionally equivalent to the following predicate device: BRIUS Software Suite (K191720 cleared April 2020).

The following table demonstrates the functional specifications of BRIUS Planner Software are substantially equivalent to the predicate devices.

Table 1: Functional Specification Comparison

Specification	BRIUS Planner Software	BRIUS Software Suite (K191720)	Comparison Result
Indication for Use	BRIUS Planner is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, treatment simulation and virtual appliance design options (Patient-Specific Nitinol Wires, Sequential Aligners, Export of Models, Indirect Bonding Transfer Media) based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the	BRIUS Software Suite is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, treatment simulation and virtual appliance design options (Patient-Specific Nitinol Wires, Export of Models, Indirect Bonding Transfer Media) based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the	Similar

	planned/desired treatment objectives. The use of the BRIUS Planner requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.	planned/desired treatment objectives. The use of BRIUS Software Suite requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.	
Technology Features	• Stand Alone Software Module • Imports Digital Patient Scans • Can be used to design Dental Casts • Useful for Diagnosis, treatment planning, and CAD design • Virtual Planning of tooth movement • Supports STL Files	• Stand Alone Software Module • Imports Digital Patient Scans • Can be used to design Dental Casts • Useful for Diagnosis, treatment planning, and CAD design • Virtual Planning of tooth movement • Supports STL Files	Same
Minimum Hardware/Soft ware Requirements	• **OS:** Windows 10 64-bit • **RAM:** 8 GB • **Monitor Resolution**:1280 X 800 • **Video Card Memory:** 1 GB • **Hard Drive Space**: 10 GB • **CPU**: Intel compatible 2.6 GHz/Dual or Quad core 2.6 GHz • **Mouse:** Any Mouse with scrolling wheel or button	• **OS:** Windows 10 64-bit • **RAM:** 8 GB • **Monitor Resolution**:1280 X 800 • **Video Card Memory:** 1 GB • **Hard Drive Space**: 10 GB • **CPU**: Intel compatible 2.6 GHz/Dual or Quad core 2.6 GHz • **Mouse:** Any Mouse with scrolling wheel or button	Same
Login Method	• Username and Password	• Username and Password	Same

Table 2. Feature Comparison Table for BRIUS Planner and K191720

Feature Comparison	BRIUS Planner	BRIUS Software (K191720)
Supported anatomic areas	Maxilla/Mandible	Maxilla/Mandible
Intended Use		
Managing Patient and case base data	Yes	Yes

Collection of study material	Yes	Yes
Alignment of study material	Yes	Yes
Measuring study material	Yes	Yes
Analyzing Study Material	Yes	Yes
Treatment Simulation	Yes	Yes
Virtual Appliance Design	Yes	Yes
Supported PC formats	Windows/Mac: Internet Browser-based	Windows/Mac: Internet Browser-based
Managing patient and case base data		
Creating, editing, deleting and copying patient data	Yes	Yes
Creating, editing, deleting and copying case data	Yes	Yes
Collection of study material		
Surface scan for intraoral scanner	Yes	Yes
Surface scan from STL file	Yes	Yes
CT image data (DICOM)	Yes	Yes
Analyzing study material		
Arch shape	Yes	Yes
Wire length	No	No
Tooth width	No	No
Bolton	No	No
Space Analysis	No	No
Overjet/Overbite	Yes	Yes
Occlusion Map	Yes	Yes
Treatment Simulation		
2D	Yes	Yes
3D	Yes	Yes
Virtual Appliance Design		
Orthodontic Appliance Search	Yes	Yes
Orthodontic Appliance Virtual Preparation	Yes	Yes
Orthodontic Appliance Design	Yes	Yes
Orthodontic appliance Export	Yes	Yes

Comparison of Indications for Use to Predicate Devices:

Based on the above comparison, the indications for use of BRIUS Planner Software is similar to that of the BRIUS Software Suite (K191720). The only change is the addition of Sequential Aligners to the appliance design options. This difference uses the same

technology to produce similar files for the production of orthodontic appliances. Therefore, BRIUS Planner Software can be considered substantially equivalent to its predicate device.

Comparison of Technological Features to Predicate Devices:

Based on the above comparison, the design, construction, and performance characteristics of BRIUS Planner Software is the same as that of BRIUS Software Suite (K191720). Therefore, BRIUS Planner Software can be considered substantially equivalent to its predicate device.

Summary of Performance Data and Substantial Equivalence:

Utilizing FDA Guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (issued May 11, 2015), BRIUS Planner Software underwent appropriate integration, verification, and validation testing.

Conclusion:

Based on comparison of indications for use, technological features, performance testing, and software validation testing, BRIUS Planner Software have been shown to be appropriate for its indications for use and is substantially equivalent to the legally marketed predicate device.