April 17, 2020

BRIUS
% Breanne Butler
Consultant
Medavice, Inc
1321 Upland Suite 6792 Dr.
Houston, Texas 77043

Re: K191720
Trade/Device Name: BRIUS Software Suite
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN
Dated: March 16, 2020
Received: March 17, 2020

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
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)*
K191720

Device Name
BRIUS Software Suite

Indications for Use *(Describe)*
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 planned/desired treatment objectives.

The use of the 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Submitter: BRIUS
4553 Westgrove Dr.
Addison TX 75001

Company Contact Person: Mehdi Roein-Peikar
Phone: (888) 755.8320
Email: mehdi@brius.com

Submission Correspondent: Medavice, Inc.
Breanne Butler, Regulatory Affairs Consultant
Address: 1321 Upland Suite 6792 Dr. Houston TX 77043
Phone: (860) 810-5594
Email: bbutler@medavice.com

Date Prepared: 04/16/2020

Proprietary Name: BRIUS Software Suite

Common Name: Orthodontic Software

Product Code: PNN – Orthodontic Software

Device Classification: Class II, 21 CFR 872.5470

Predicate Devices: 3Shape OrthoSystem (K171634)

Device Description:

The BRIUS Software Suite is an orthodontic appliance design and treatment simulation software. Until recently, this software was used only as a manufacturing software for nitinol wires, indirect bonding transfer media, and export of models. This software is now for use 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 patient-specific nitinol wires, indirect bonding transfer media, and export of models using standard stereolithographic (STL) and drawing exchange format (DXF) files for the design of custom shape-set nitinol wires. A 2D rendering of the nitinol wires needed for the patient can be created in the form of a DXF file and a 3D representation of the ideal tooth

alignment for the patient can be created in the form of an STL file. The 2D rendering can then be used to laser cut a nitinol sheet to form a 2D version of the patient-specific nitinol wire shape. Finally, a high-temperature mold can be fabricated from the STL file to shape set the 2D cut nitinol wire for a specific fit for patients.

Indications for Use:

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 planned/desired treatment objectives.

The use of the 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.

Comparison to Predicate Devices:

BRIUS Software Suite is functionally equivalent to the following predicate device: 3Shape OrthoSystem (K171634 cleared January 31st, 2017).

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

Table 1: Functional Specification Comparison

Specification	**BRIUS Software Suite**	**3Shape OrthoSystem**	***Comparison Result***
Indication for Use	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	The 3Shape Ortho System™ is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Custom Metal Bands, 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	Similar

	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 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.	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 Ortho System™ 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/Software 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 7, 8, 10 64-bit • **RAM:** 8 GB • **Monitor Resolution**:1280 X 800 • **Video Card Memory:** 1 GB • **Hard Drive Space**: 10 GB • **CPU**: Intel Core i5 or equivalent • **Mouse:** with wheel button	Similar; No effect to the indication for use.
Login Method	• Username and Password	• Username and Password	Same

Table 2. Feature Comparison Table for BRIUS and 3Shape

Feature Comparison	BRIUS	3Shape (K171634)
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
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)	No	Yes
2D overlay (PNG, JPG, BMP)	No	Yes
Alignment of study material		
Aligning surface scan and CT image	No	Yes
Aligning Cephalometric Images	No	Yes
Alignment of 2D overlays	No	Yes
Ability to check/adjust DICOM visibility	No	Yes
DICOM scan Segmentation	No	No
2D Measurement tool box	No	Yes
3D Measurement tool box	No	Yes
Analyzing study material		
Arch shape	Yes	Yes
Wire length	No	Yes
Tooth width	No	Yes
Bolton	No	Yes
Space Analysis	No	Yes
Overjet/Overbite	Yes	Yes

Occlusion Map	Yes	Yes
Treatment Simulation		
2D	Yes	Yes
3D	Yes	Yes
Virtual Appliance Design		
Orthodontic Appliance Search	No	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 the BRIUS Software Suite is similar to that of the 3Shape OrthoSystem. The 3Shape system is different in that it produces custom metal bands while the BRIUS system produces patient-specific nitinol wires. Otherwise, the indications for use for both devices are similar. Therefore, the BRIUS Software Suite 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 the BRIUS Software Suite is similar to that of 3Shape OrthoSystem. The BRIUS system does not include some measurement and search tools which are included in the 3Shape system. These tools do not affect the ability of users to perform necessary functions within the software. Additionally, both systems use CAD/CAM technology to produce digital models patient-specific orthodontic devices. Therefore, the BRIUS Software Suite can be considered substantially equivalent to its predicate devices.

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), the BRIUS Software Suite underwent appropriate integration, verification, and validation testing.

Conclusion:

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