Orchestrate 3D
% Bill Jacqmein
Consultant
JCQ Consulting
11218 Zest Court NE
Blaine, Minnesota 55449

11.26.18

Re: K181112
Trade/Device Name: Orchestrate 3D
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN
Second Product Code: LLZ
Dated: October 17, 2018
Received: October 23, 2018

Dear Bill Jacqmein:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2018.11.26 07:57:41 -05'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K181112

Device Name
Orchestrate 3D

Indications for Use *(Describe)*

The Orchestrate 3D Orthodontic Software is indicated for use as a front-end software tool for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options, including dental casts, which may be used for sequential aligner trays or retainers. These applications are 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 Orchestrate 3D 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.

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Section 5. 510(k) Summary

K181112

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter: Orchestrate 3D
1747 North Riverside Ave
Rialto, CA 92376

Company Contact Person: Todd Ehrler, DDS, MS
Phone: (888) 755.8320
Email: Todd.Erhler@orchestrate3d.com

Submission Correspondent: Bill Jacqmein, Regulatory Affairs Consultant
Address: 11218 Zest Ct. NE, Blaine, MN 55449
Phone: (404) 216-6190
Email: bjacqmein@rcqsolutions.com

Date Prepared: October 17, 2018

Proprietary Name: Orchestrate 3D Orthodontic Software

Common Name: Orthodontic Plastic Brackets (Software)

Product Code: PNN – Orthodontic Plastic Brackets, LLZ – System, Image Processing, Radiological

Device Classification: Class II, 21 CFR 872.5470

Primary Predicate Devices: 3Shape Ortho System (K171634)

Device Description:

The Orchestrate 3D Orthodontic Software is an orthodontic appliance design and treatment simulation software. This software is for use by Dental professionals to diagnose and design solutions for patients. Digital scans (3D) of a patient denture can be loaded into the software and the dental professional can then create treatment plans for each individual patient and their needs. The system can be used to fabricate dental casts using standard stereolithographic (STL) files for use in 3D printers. Dental casts printed can then be used to manufacture sequential aligner trays and retainers.

Indications for Use:

The Orchestrate 3D Orthodontic Software is indicated for use as a front-end software tool for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options, including dental casts, which may be used for sequential aligner trays or retainers. These applications are 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 Orchestrate 3D 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:

Orchestrate 3D Orthodontic Software is functionally equivalent to the following predicate device: 3Shape Ortho System (K171634) cleared January 17th, 2018).

The following table demonstrates the functional specifications of Orchestrate 3D Orthodontic Software are substantially equivalent to the predicate devices.

Table 1: Functional Specification Comparison

Specification	***Orchestrate 3D Orthodontic Software***	**3Shape Ortho System (K171634)**	***Comparison Result***
Indication for Use	The Orchestrate 3D Orthodontic Software is indicated for use as a front-end software tool for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options, including dental casts, which may be used for sequential aligner trays or retainers. These applications are 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 Orchestrate 3D requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have	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 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	Similar

	received a dedicated training in the use of the software.	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	Same
Login Method	• None Required; Uses Windows 10 Log in Security for User ID	• Username and Password	Similar; No effect to the indication for use.

Table 2: Feature Comparison Table for Orchestrate 3D and 3Shape

Feature Comparison	**Orchestrate 3D**	**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	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	No	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 Orchestrate 3D Orthodontic Software is similar to that of the 3Shape Software. Therefore, the Orchestrate 3D Orthodontic 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 the

Orchestrate 3D Orthodontic Software is similar to that of 3Shape Software. Therefore, the Orchestrate 3D Orthodontic Software 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 Orchestrate 3D Orthodontic Software underwent appropriate integration, verification, and validation testing. The software passed the testing and performed per its intended use.

Conclusion:

Based on comparison of indications for use, technological features, performance testing, and software validation testing, the Orchestrate 3D Orthodontic Software have been shown to be appropriate for its indications for use and is substantially equivalent to the legally marketed predicate device.