December 16, 2021

ArchForm, Inc
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K213916
Trade/Device Name: ArchForm Orthodontic Software System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: PNN, LLZ
Dated: December 13, 2021
Received: December 15, 2021

Dear Dave Yungvirt:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213916

Device Name
ArchForm Orthodontic Software System

Indications for Use *(Describe)*

The ArchForm Orthodontic Software System 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 ArchForm Orthodontic Software 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.

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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K213916

510(k) Summary

ArchForm Orthdontic Software System

Submitter: ArchForm,Inc.
8421 Blue Heron Drive
Bakersfield, CA 93312

Contact Person: Andrew S. Martz
Phone: 661-304-8575
andrew@archform.co

Date Prepared: December 10, 2021

Trade Name: ArchForm Orthodontic Software System

Classification Name: Orthodontic Plastic Brackets (Software)

Device Class: Class II

Regulation Number: 21 CFR 872.5470

Product Code: PNN

Review Panel: Dental

Predicate Device: Orchestrate 3D Orthodontic Software – K181112

Device Description: The ArchForm Orthodontic Software System 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's dentition 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 ArchForm Orthodontic Software System 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 ArchForm Orthodontic Software 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.

Substantial Equivalence Discussion:

The ArchForm Orthodontic Software System is functionally equivalent to the Orchestrate 3D Orthodontic Software predicate device (K181112) cleared November 26, 2018). The following table demonstrates that the functional characteristics of the ArchForm Orthodontic Software System are substantially equivalent to the predicate device.

Comparison of Indications for Use to Predicate Device:

Based on the comparison below, the indications for use of the ArchForm Orthodontic Software System is similar to that of the Orchestrate 3D Orthodontic Software. Therefore, the ArchForm Orthodontic Software System can be considered substantially equivalent to its predicate device.

Comparison of Technological Features to Predicate Device:

Based on the comparison below, the design, construction, and performance characteristics of the ArchForm Orthodontic Software System is similar to that of Orchestrate 3D Orthodontic Software. Therefore, the ArchForm Orthodontic Software System 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, 2005), the ArchForm Orthodontic Software System underwent appropriate integration, verification, and validation testing. The software passed the testing and performed per its intended use.

Substantial Equivalence Comparison

Characteristic	ArchForm Orthodontic Software System	Orchestrate 3D Orthodontic Software	Comparison
510(k) Number	**TBD** (K213916)	**K181112**	**N/A**
Class	Class II	Class II	Same
Device Classification Name	Orthodontic Plastic Brackets (Software)	Orthodontic Plastic Brackets (Software)	Same
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	Same
Product Code	PNN	PNN	Same
Indications for Use	…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 ArchForm Orthodontic Software 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.	…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 Orthodontic Software 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.	Same
Technological Features	• Stand Alone Software • 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 • 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

Characteristic	ArchForm Orthodontic Software System	Orchestrate 3D Orthodontic Software	Comparison
Minimum Hardware / Software Requirements	• **OS:** Windows 10 and MacOS Catalina • **RAM:** 4 GB • **Monitor Resolution**: 1280 X 720 • **Video Card:** HD620 • **Hard Drive Space**: 128 GB • **CPU**: Intel 2nd Gen Core i5 processor or equivalent • **Mouse:** with wheel 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 compatible 2.6 GHz/Dual or Quad Core 2.6 GHz • **Mouse:** with scrolling wheel or button*	Same
Supported Anatomic Areas	Maxilla/Mandible	Maxilla/Mandible	Same
Intended Use **Managing Patient and case base data**	Yes	Yes	Same
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	
Surface scan for intraoral scanner	Yes	Yes	
Surface scan from STL file	Yes	Yes	

Characteristic	ArchForm Orthodontic Software System	Orchestrate 3D Orthodontic Software	Comparison
Analysis and Treatment			
Arch Shape	Yes	Yes	
Overbite / Overjet	Yes	Yes	
Occlusal Map	Yes	Yes	
3D Treatment Simulation	Yes	Yes	
Orthodontic Appliance Virtual Preparation	Yes	Yes	Same
Orthodontic Appliance Design	Yes	Yes	
Orthodontic Appliance Export	Yes	Yes	

Conclusion: Based on comparison of indications for use, technological features, performance testing, and software validation testing, the ArchForm Orthodontic Software System has been shown to be appropriate for its indications for use and is substantially equivalent to the legally marketed predicate device.