May 11, 2020

ArcadLab
℅ Patsy Trisler
Regulatory Consultant
Qserve Group US, Inc.
7949 Beaumont Green East Drive
Indianapolis, Indiana 46250

Re: K192244
Trade/Device Name: Arcad SmileStudio and Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC, PNN
Dated: April 3, 2020
Received: April 6, 2020

Dear Patsy Trisler:

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)*
K192244

Device Name

Arcad SmileStudio and Aligner System

Indications for Use *(Describe)*

The Arcad SmileStudio 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 design of a series of dental casts, which may be used for sequential aligner trays or retainers, 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 Arcad Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The Arcad Aligner System positions teeth by way of continuous gentle force.

The use of the Arcad Aligner System and SmileStudio requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well 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 Name:	ArcadLab, LLC
Submitter Address:	1860 Old Okeechobee Road, Suite 402 West Palm Beach, FL 33409
Email Address:	ecano@arcadlab.com
Contact Person:	Emerson Cano President
Date Prepared:	April 3, 2020
Device Trade Name:	Arcad SmileStudio and Aligner System
Common Name	Aligner, Sequential

Predicate Devices

	Predicate A	Predicate B
Classification Name	Orthodontic Software	Orthodontic Plastic Bracket
Number	21 CFR 872.5470	21 CFR 872.5470
Product Code	PNN	NXC
Regulatory Class	2	2
Predicate Name	K180941, 3Shape Ortho System™; 3Shape A/S	K113618, ClearCorrect System, ClearCorrect, LLC

Reference Device: K080227, OrthoCAD iQ; Cadent, Inc.

Indications for Use Statement:

The Arcad SmileStudio 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 design of a series of dental casts, which may be used for sequential aligner trays or retainers, 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 Arcad Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The Arcad Aligner System positions teeth by way of continuous gentle force.

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

Device Description and Summary of Technological Characteristics

The Arcad SmileStudio software is an orthodontic diagnosis and treatment simulation software for use by dental professionals. SmileStudio imports patient 3-D digital scans and allows the user to diagnose the orthodontic treatment needs of the patient and develop a treatment plan. The output of the treatment plan may

be downloaded as files in standard stereolithographic (STL) format for fabrication of dental casts, which may be used to fabricate sequential aligner trays or retainers.

The Arcad Aligner System is a series of customized clear plastic removable aligners that are fabricated from a clear, thin thermoformed polyurethane. The aligners are designed to gradually move the patient's teeth incrementally, repositioning them from their original misalignment to a more aligned state.

ArcadLab manufactures the customized aligners based on either standard impressions or intraoral scans sent to the company by the prescribing dentist or orthodontist. Arcadlab manufactures models from the impressions and those models are scanned using standard validated software. The digital files are used to produce the aligner series with the thermoplastic polyurethane.

The packaged aligners are sent to the dental clinician who then distributes them in sequential stages to the patient and follows up with the patient through orthodontic examinations to check device fit and function.

The thermoplastic material used for fabrication of the aligners is commonly used in many dental appliances, including the predicate aligners.

Mechanism of Action

Based on the clinician's treatment plan, each aligner is used for a prescribed period of time to exert gentle force to achieve the realignment of teeth over a period of time.

Device Testing

<u>Laboratory Testing</u>

Test data were submitted to validate the processes used for the design and manufacture of the clear customized aligners.

Testing to verify and validate the Arcad SmileStudio software was included in the premarket notification.

<u>Biocompatibility</u>

The following ISO 10993 testing was performed according to Good Laboratory Practices to assess the safety and biocompatibility of the thermoplastic material:

Part 3 (Bacterial Mutagenicity – Ames Assay)
Part 5 (Cytotoxicity Elution - MEM),
Part 10 (Intracutaneous/Intradermal) Reactivity),
Part 10 (Oral Mucosa Irritation),
Part 10 (Maximization for Delayed-Type Hypersensitivity),
Part 11 (Subacute Systemic Toxicity)

This testing has shown that the material is safe and biocompatible for the stated intended use.

Animal | Human Testing

No animal or human testing are required for this product because it is composed of the same materials, is designed similarly, and is manufactured by method similar to the predicate device.

Comparison to Predicate Devices:

There are no notable differences comparing the Arcad aligner system to the ClearCorrect aligner and 3Shape software predicate devices (see SE Comparison Table below):

- The intended use is the same.
- The mechanisms of action (software and aligner systems) are the same.
- The polyurethane material used to make the aligners is the same.
- The method of manufacture and customizing the aligners is similar.
- The software used during the planning and manufacturing processes is similar.

Substantial Equivalence Conclusion

Based on the documentation presented in the 510(k), as summarized above and shown on the SE Comparison Table, it can be concluded that this software system and the clear aligners are substantially equivalent to the predicate devices.

Trade Name:	**Arcad Lab Aligner and Arcad Smile Studio**	**Predicate A 3Shape Ortho System**	**Predicate B ClearCorrect System™**
510(k) #	K192244	K180941	K113618
Manufacturer	ArcadLab, LLC	3Shape A/S	ClearCorrect, LLC
Classification name 21 CFR Product Code Class	Orthodontic plastic bracket 852.5470 NXC 2	Orthodontic Software - 852.5470 PNN 2	Orthodontic software 852.5470 NXC 2	Orthodontic plastic bracket 852.5470 PNN 2
Intended Use	The ArcadLab SmileStudio 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 design of a series of dental casts, which may be used for sequential aligner trays or retainers, 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	Ortho System™ for dental retainers and dental case for sequential aligners 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 based on 3D models of the patient's dentition before the start of an orthodontic treatment.	The ClearCorrect System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The Clear Correct System positions teeth by way of continuous gentle force.

	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 ArcadLab Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The ArcadLab Aligner System positions teeth by way of continuous gentle force. The use of the ArcadLab SmileStudio and Aligner System requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well to have received a dedicated training in the use of the software.	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.	The ClearCorrect System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The Clear Correct System positions teeth by way of continuous gentle force.
Mode of Action of customized aligner	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays.	N/A	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays.
Method of Use	Each preformed plastic tray is worn by the patient as prescribed by the dental practitioner, usually a few weeks prior to using the next sequential aligner tray. The software is used by Dental Professionals in orthodontic treatment planning (before, during, after treatment) covering management of patients and models, inspection, 2D and 3D measurement, orthodontic analysis of models, 2D & 3D treatment simulation, as well as virtual appliance preparation, handling and export. Also provides CAM output for 3D printers and milling machines.	The software is used by Dental Professionals in orthodontic treatment planning (before, during, after treatment) covering management of patients and models, inspection, 2D and 3D measurement, orthodontic analysis of models, 2D & 3D treatment simulation, as well as virtual appliance preparation, handling and export. Also provides CAM output for 3D printers and milling machines.	Each preformed plastic tray is worn by the patient as prescribed by the dental practitioner, usually a few weeks prior to using the next sequential aligner tray.

Material	Thin thermoformed polyurethane	N/A	Thin thermoformed polyurethane
Biocompatible	Yes	N/A	Yes
OTC or Rx	Rx	Rx	Rx
Software	Yes – system includes software	Yes – product is software	No – system does not include software