June 7, 2019

Argen Corporation
Mr. Paul Cascone
Senior Vice President, Research and Development
% Patsy Trisler
Regulatory Consultant
Qserve Group US, Inc.
5600 Wisconsin Avenue, #509
Chevy Chase, Maryland 20815

Re: K183229
Trade/Device Name: Argen Clear Aligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: May 6, 2019
Received: May 8, 2019

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,

Srinivas Nandkumar, Ph.D.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K183229

Device Name

Argen Clear Aligner

Indications for Use *(Describe)*

The Argen Clear Aligner is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The aligner positions teeth by way of continuous gentle force.

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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510(k) Summary
K183229

Submitter Name:	Argen Corporation
Submitter Address:	5855 Oberlin Drive San Diego, CA 92121
Phone Number:	858-455-7900
Contact Person:	Mr. Paul Cascone Senior Vice President, Research and Development
Date Prepared:	June 5, 2019
Device Trade Name:	Argen Clear Aligner
Common Name	Aligner, Sequential
Classification Name Number Product Code Regulatory Class	Orthodontic Plastic Bracket 21 CFR 872.5470 NXC 2
Primary Predicate Device:	K981095; The Align System; Align Technology, Inc.
Reference Devices:	K180941; Ortho System™; 3Shape A/S K062828; Mouthguard and Aligner Materials, Dentsply International
Indications for Use Statement	The Argen Clear Aligner is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The aligner positions teeth by way of continuous gentle force.
Device Description and Summary of Technological Characteristics	The Argen Clear Aligner is comprised of a series of clear plastic removable aligner trays that are designed to correct tooth malocclusions without the use of conventional wire and bracket orthodontic technology. A dental health professional (e.g. orthodontist or dentist) prescribes the Argen Clear Aligner based on an assessment of the patient's teeth, determines a course of treatment with the system, and completes a prescription form using a standard dental software used for tooth alignment. The series of plastic trays are designed in accordance with the physician's prescription using standard dental software for planning the tooth alignment. The software system used is Ortho Analyzer, 2019 ver 1.8.1.0 by 3Shape A/S (K180941). It is used for management of 3D scanned orthodontic models, orthodontic diagnosis by measuring, analyzing, inspecting and visualizing 3D scanned orthodontic models, virtual planning of orthodontic treatments by simulating tooth movements, and design of orthodontic appliances based on 3D scanned orthodontic models.

The prescribing physician reviews and approves the model scheme before the molds are produced. Once approved, Argen produces trays, which are formed of clear, thin, thermoformed plastic. The trays are provided to the dental health care professional who provides them to the patient, confirming fit and design.

The thermoplastic material used in the manufacture of the Argen aligners is similar to the material commonly used in many dental and orthodontic appliances including clear aligners.

Mechanism of Action

The mechanism of action is similar to the predicate device. Orthodontic tooth movement, achieved over time with the clear aligner systems, occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on the dental professional's prescription. The trays are held in place by pressure and can be removed by the patient at any time.

Device Testing

Non-Clinical Performance Testing:
Reference Dentsply's K062828.

Biocompatibility Testing:
Reference Dentsply's K062828.

Animal | Human Testing

Animal and human performance testing are not required for this product type.

Comparison to Predicate Device:

A comparison of the Argen Clear Aligner to the predicate device shows the following (See Substantial Equivalence Comparison Table on last page of this Summary):

- The indications for use is similar.
- The mechanism of action is similar.
- The polyurethane used to make the aligners is similar to the predicate device, a single-layer thermoformable material:
- Dental software is used in the design and manufacture of both Argen Clear Aligner and the predicate.
- The method of manufacture and customizing the aligners is similar.

Substantial Equivalence Conclusion

There are no notable differences between the Argen Clear Aligner and the predicate. Therefore it can be concluded that the Argen Clear Aligner is substantially equivalent to the Align Technology predicate device.

Substantial Equivalence Comparison

Trade Name:	Argen Clear Aligner	The Align System
510(k) Number	K183229	K981095
Manufacturer	Argen Corporation	Align Technology, Inc.
Classification # & Product Code Class	21 CFR 852.5470 NXC 2	21 CFR 852.5470 NXC 2
Intended Use	The Argen Clear Aligner is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The aligner positions teeth by way of continuous gentle force.	The Align System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The Align System positions teeth by way of continuous gentle force.
Mode of Action	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays.	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.	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.
Polymer Material(s)	Thermoformable polymer single layer	Thermoformable polymer single layer
Mechanical Performance Testing:	Reference: Dentsply: K062828	Reference: Dentsply: K062828
Biocompatibility Testing	Yes	Yes
OTC or Rx	Rx	Rx
Software Use	Yes	Yes
Sterile	No	No