February 10, 2020

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

Re: K192846
Trade/Device Name: Argen Clear Aligner, Argen Clear Aligner Premium
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: January 10, 2020
Received: January 13, 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K192846

Device Name

Argen Clear Aligner and Argen Clear Aligner Premium

Indications for Use *(Describe)*

The Argen Clear Aligner and Argen Clear Aligner Premium are 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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SECTION 5

510(k) SUMMARY

I. SUBMITTER	
Submitter Name:	Argen Corporation
Submitter Address:	5855 Oberlin Drive San Diego, CA 92121
Contact Person: **Telephone #:**	Mr. Paul Cascone Senior Vice President, Research and Development 858-455-7900
Date Prepared:	January 17, 2020
II. DEVICE	
Device Trade Name:	Argen Clear Aligner and Argen Clear Aligner Premium
Common Name:	Aligner, Sequential
Classification Name **Number** **Product Code** **Regulatory Class**	Orthodontic Plastic Bracket 21 CFR 872.5470 NXC 2
Review Panel	Dental
III. PREDICATE DEVICE	Primary Predicate: K183229, Argen Clear Aligner, Argen Corporation Reference Devices: K113618, ClearCorrect LLC, ClearCorrect System K182826, Ormco Spark Aligner System, Sybron Dental Specialties K180941 Ortho System™, 3Shape A/S
IV. DEVICE DESCRIPTION and SUMMARY OF TECHNOLOGICAL CHARACTERISTICS	The Argen clear aligners are comprised of 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 or the Argen Clear Aligner Premium based on an assessment of the patient's teeth. The dental health professional (dentist/orthodontist) takes intraoral scans or physical impressions 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 materials used in the manufacture of the Argen aligners are similar to the materials commonly used in many dental and orthodontic appliances including clear aligners. The Argen Clear Aligner is made of a thermoplastic polyurethane resin and the Argen Clear Aligner Premium is made of a thermoplastic polyurethane-polyester composite resin.
V. INDICATIONS FOR USE	The Argen Clear Aligner and Argen Clear Aligner Premium are 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.
VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES	The Argen clear aligners have the same intended use as the predicate and reference devices. There are no fundamental technological differences between the Predicate and the modified device. The only modification(s) are as noted – different thermoplastic materials than used for the predicate aligner. Comparison Tables A (for the Argen Clear Aligner) and B (for the Argen Clear Aligner Premium) follow on the next pages.
VII. SUMMARY OF PERFORMANCE DATA AND DESIGN CONTROLS	A Risk Analysis was performed according to ISO 14971:2012 and documentation was included in the 510(k) to assess the modification and the impact on performance and safety. Physical properties and Biocompatibility testing were referenced in the Predicate device and the two Reference device submissions. Verification and validation activities were assessed on the proposed device to ensure consistency between the aligner series' design and manufactured aligners. The results show the proposed device met all pre-defined acceptance criteria.
VIX. SUBSTANTIAL EQUIVALENCE CONCLUSION	The information and data provided in this Special 510(k) establish that the modified device is substantially equivalent in the intended use, design, principle of operation, technology, and materials to the predicate.

Table A – Substantial Equivalence Comparison
[For proposed Argen Clear Aligner]

	Predicate Device K183229	Proposed Device K192846	Reference Device K113618
Device Name	Argen Clear Aligner	Argen Clear Aligner	Clear Correct System
Manufacturer	Argen Corporation	Argen Corporation	Clear Correct, LLC
Classification Name **Product Code** **Class**	21 CFR 872.5470 Orthodontic Plastic Bracket NXC 2	Same	Same
Indications for 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.	Same	Same
Mode of Action	The appliance applies gentle forces on teeth according to the plan prescribed by the doctor.	Same	Same
Description of Use	Each removable preformed plastic tray is worn by the patient as prescribed by the doctor, usually a few weeks prior to using the next sequential aligner tray.	Same	Same
Material	Thermoplastic polyurethane resin	Same	Same
Software Used for Treatment Planning/ Manufacture	Yes	Same software	Yes
Prescription Use	Rx	Same	Same
Biocompatibility	Yes, shown to meet requirements	Same	Same
Verification and Validation Testing	Yes, performed	Yes, performed	Presumed performed

Table B – Substantial Equivalence Comparison
[For proposed Argen Clear Aligner Premium]

	Predicate Device K183229	Proposed Device K192846	Reference Device K182826
Device Name	Argen Clear Aligner	Argen Clear Aligner Premium	Ormco™ Spark™ Aligner System
Manufacturer	Argen Corporation	Argen Corporation	Sybron Dental Specialties
Classification Name **Product Code** **Class**	21 CFR 872.5470 Orthodontic Plastic Bracket NXC 2	Same	Same
Indications for 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.	Same	Same
Mode of Action	The appliance applies gentle forces on teeth according to the plan prescribed by the doctor.	Same	Same
Description of Use	Each removable preformed plastic tray is worn by the patient as prescribed by the doctor, usually a few weeks prior to using the next sequential aligner tray.	Same	Same
Material	Thermoplastic polyurethane polyester composite resin	Same	Same
Software Used for Treatment Planning/ Manufacture	Yes	Same software	Yes
Prescription Use	Rx	Same	Same
Biocompatibility	Yes, shown to meet requirements	Same	Same
Verification and Validation Testing	Yes, performed	Yes, performed	Presumed performed