February 26, 2021

Utah Medical Products and Services
Brandon Farley
Business Owner and President
DBA Cottonwood Laboratories
6526 South State Street Suite #301
Murray, Utah 84107

Re: K173738
Trade/Device Name: Archworx
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: January 14, 2021
Received: January 19, 2021

Dear Brandon Farley:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173738

Device Name
Archworx

Indications for Use *(Describe)*

Archworx is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). Archworx is intended to position 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.

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.

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"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."

Due to the updates within this submission, a 510K Summary Table is provided:

Manufacturer Name/Submitter	Utah Medical Products and Services (DBA Cottonwood Laboratories)
Name	Brandon Farley
Phone Number and Address	(801) 904-2006 6526 State Street Murray, UT 84107
Device Name	Archworx
510K Number	K17378
Device Classification Name	Orthodontic Plastic Brackets (Sequential Aligners)
Regulation Number	21 CFR 872.5470
Product Classification Code	NXC
Product Class	2
Review Panel	Dental
Prescription or Over the Counter	Prescription
Supplied Sterile	No
Single Patient Use	Yes
Physical Properties/Image	
Concise Description	Devices are intraoral thermoformed plastic aligner trays for tooth malocclusion correction.
Indications for Use Statement	Archworx is indicated for the treatment of tooth malocclusion in patients with full, permanent dentition (i.e., all second molars). Archworx is intended to position teeth by way of continuous gentle force.
Intended Use	Archworx are a series of sequential aligner trays used to treat malocclusion in patients with full, permanent dentition by way of continuous gentle force; used under the direction of a Prescribing Dentist or Orthodontist.
Length of Time Aligners Are to Be Worn	Typical use is 20-22 Hours Per Day, Full-Time, except for eating and cleaning.

Device Duration	Permanent Duration Contact (Greater Than 30-Days)
Schedule of Use	Aligners are used in a sequence with each aligner allowing for tooth movement by using a gentle continuous force to the final, aligned tooth position.
Mechanism of Action	Prescribing Dentist or Orthodontist approved customized appliances that move teeth in small increments from their original misaligned and malposed state to a final aligned state.
Method of Fabrication	Aligners are manufactured based on impressions or scans sent to the manufacturer by the Prescribing Dentist or Orthodontist after the Prescribing Dentist or Orthodontist; or clinician has performed a clinical assessment of the patient's teeth, taken intraoral scans or impressions of the patients teeth and designed a treatment plan.
Method of Treatment	Prior to the start of the aligner manufacturing process and printing the 3D Models, the lab formulates the aligner treatment plan which is sent to the Prescribing Dentist or Orthodontist for review and approval and that only after approval of the treatment plan is the fabrication process started.
Software Used	Models are fabricated after the impressions which are then scanned using the 3Shape Ortho System Software (K180941); and the applications used are the Appliance Designer and the Ortho Analyzer.
Material of Fabrication	Thermoformed Polycarbonate (Plastic) - Digital files are used to produce the aligners series using Zendura FLX.
Fabrication	Plastic disk is thermoformed over the model, then aligners are inspected, cleaned and trimmed.
Distribution	Aligners are sent directly to the Prescribing Dentist or Orthodontist for dispensing to patience in sequential stages where the Prescribing Dentist or Orthodontist monitors the patient throughout the entire treatment process.
Biocompatibility	Biocompatibility testing was conducted by the material manufacturer for cytotoxicity, sensitization, irritation, and oral mucosal irritation according to the ISO 10993

	standards and that the device met the acceptance criteria for all tests.
Bench Performance Testing	Physical properties testing was conducted, and testing information was obtained from the material manufacturer. All the physical properties testing met the pre-specified acceptance criteria.
Verification and Validation Testing	Yes, Performed. For 3 different patient cases, aligners were evaluated at 3 different points through the sequence for each sequence point, 3 critical dimensions based on intended positions of these critical tooth structures. Testing indicated the aligner designed in the software meets the planned location, positions and all dimensions as expected; and as prescribed.
Primary Predicate	Argen Clear Aligner and Argen Clear Aligner Premium (K192846)
Reference Device	3Shape Ortho System Software (K180941)

Conclusion

Comparison of the Proposed Device and the Primary Predicate Device demonstrate:

- Indications for Use
- Mechanism of Action
- Length, Duration, and Schedule of Use
- Design technology
- Material
- Fabrication and composition

of Archworx, is substantially equivalent to the Primary Predicate Device; Argen Clear Aligner and Argen Clear Aligner Premium (K192846).