August 12, 2022

Arklign Laboratories
℅ Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030-0172

Re: K220835
Trade/Device Name: Arkligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: June 1, 2022
Received: June 13, 2022

Dear Angela Blackwell:

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 and
ENT 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)*

K220835

Device Name
Arkligners

Indications for Use *(Describe)*

Arkligners are indicated for use in the alignment of permanent teeth (i.e. all second molars) through orthodontic treatment of misalignment and malocclusion. The aligners guide teeth to their final position by way of continuous gentle forces.

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.

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K220835

Arkligners

510K Summary

March 10, 2022

Name and Address: Arklign Laboratories
2526 Qume Dr Suite 15
San Jose, CA 95131
Contact Person: Rex Ho
Email: rho@arklign.com
Telephone: (800) 361 1659
Website: www.arklign.com

Name of device: Arkligners
Common name: Sequential aligners
Classification Name: Orthodontic Plastic Bracket
CFR: 21 CFR 872.5470
Primary Product Code: NXC
Class: II
Submission Contact:

Angela Blackwell
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P.O. Box 718
Gresham, OR 97030-0172
(704)450-9934
angela@blackwelldevice.com

Device Description: The Arkligners device is fabricated of clear thin thermoformed Essix Ace plastic in sequential series to progressively reposition the teeth. Corrective force to straighten the teeth is delivered via minor changes into a position in each subsequent aligner.

Clinicians scan a patient, export the views needed for the patient model, and sends these scans to Arklign Laboratories. They import them into 3Shape Dental Manager 2020 to create a patient model. The patient model is imported into 3Shape Ortho System 2021 Clear Aligner Studio to design the models to make clear aligners for the treatment plan the clinician has ordered. This treatment plan (with models needed to make aligners for whichever treatment phases are being ordered) is then exported and sent to the clinician along with the original patient model file for them to approve. Then Arklign Laboratories exports the approved models needed to make the specific aligners ordered to Formlabs Form 2 3D printer running Formlabs PreForm 3.12.0. The aligner is thermoformed over the printed model. Every aligner is checked for fit on the printed patient model before sending to the clinician.

Indications for Use: Arkligners are indicated for use in the alignment of permanent teeth (i.e. all second molars) through orthodontic treatment of misalignment and malocclusion. The aligners guide teeth to their final position by way of continuous gentle forces.

Technological Characteristics:

Treatment of tooth malocclusions via a series of intraoral plastic appliances designed to provide forces for incremental movement of targeted teeth to a desired final position is the technological principle for both the subject device and the predicate device.

Mechanism of Action:

The mechanism of action is similar to the predicate devices. Orthodontic targeted tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a dental health professional's prescription.

Testing Summary: The material used for the Arkligners is Essix Ace 1mm thick disks. This same Dentsply Esssix Ace was cleared In K062828 and the same material is used in the predicate device BRIUS Clear Aligners. Literature studies show this material has sufficient wear properties for this indication. Literature studies used the same thickness of Essix Ace (1mm).

A biocompatibility assessment of Essix Ace was evaluated during its 510k clearance. A cytotoxicity test was conducted to show the contact of the Essix Ace disk with the model made from Formlabs Draft Resin V2 did not change the non-cytotoxic nature of the Essix Ace.

Arklign conducted manufacturing validation with 3Shape Ortho System 2021 Clear Aligner Studio being used to fabricate the models used to produce aligners and based upon patient scans representing three specific clinical scenarios. Clinicians working with Arklign determined the treatment plan. The software used to create the original digital patient model was 3Shape Dental Manager 2020. This model was exported to the 3Shape Ortho System 2021 Clear Aligner Studio for creation of the models to form aligners over. Once the models to form aligners were designed then the designs were exported to Formlabs PreForm 3.12.0 being run on a Formlabs Form 2 3D printer and printed using Formlabs Draft Resin V2.

Arkligners were created over the models by using a Scheu-Dental BioStar thermoforming machine. Settings for this thermoforming machine for Essix Ace 1mm thick disks are found in the instructions for use accompanying the Essix Ace disks. Arkligners were checked for fit on the relevant patient model by lab personnel doing measurements and two clinicians using clinical criteria for fit.

Predicate Device: K202792 BRIUS Clear Aligners

Reference Devices: K062828 Dentsply Essix

Substantial Equivalence:

Device	Arkligners	BRIUS Clear Aligners K202792	Dentsply Essix K062828
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	unclassified
Device Classification Name/Device Common Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Prescription mouthguard/Mouthguard and Aligner Materials
Product Code	NXC	NXC	MQC
Classification	II	II	unclassified
Indications for use	Arkligners are indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The aligners position teeth by way of continuous gentle force.	BRIUS Clear Aligners are indicated for use in the alignment of permanent teeth (i.e. all second molars) through orthodontic treatment of misalignment and malocclusion. The aligners guide teeth to their final position by way of continuous gentle forces.	MOUTHGUARD AND ALIGNER MATERIALS are indicated for the fabrication of orthodontic and dental appliances such as aligners, bite planes, mouthguards, nightguards, snoring appliances, splints, retainers, repositioners, and temporary bridges.
Mode of action	Orthodontic tooth movement occurs through forces applied	Orthodontic tooth movement occurs through forces applied	

	by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	
Material	Dentsply Essix Thickness of 1mm	Dentsply Essix Thickness of ¾, 7/8 and 1 mm	Dentsply Essix Ace Thicknesses of ¾, 7/8 and 1 mm

Conclusion: Based on materials, technological characteristics, mechanism of action, indications for use and the results of non-clinical performance testing, Arkligners are substantially equivalent to BRIUS Clear Aligners K202792.

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