October 13, 2022

CreoDent Prosthetics LTD
℅ April Lee
Regulatory Affairs Consultant
Withus Group Inc.
106 Superior,
Irvine, CA 92620

Re: K211427
Trade/Device Name: CREOKORREKT Aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: September 14, 2021
Received: September 15, 2021

Dear April Lee:

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 Michael E. Adjodha, M. ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
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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)*
K211427

Device Name
CREOKORREKT Aligners

Indications for Use *(Describe)*
The CREOKORREKT 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

This summary is being submitted in accordance with requirements of 21 CFR Part 807.92.

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Device Information

- Proprietary Name: CREOKORREKT Aligners
- Common Name: Orthodontic Sequential Aligner
- Classification Name: Orthodontic plastic bracket
- Classification: Class II, 21 CFR 872.5470
- Classification Product Code: NXC
- Panel: Dental
- Date Prepared: 10/12/2022

Predicate Devices:
Primary Predicate
K192846, Argen Clear Aligner by Argen Corporation

Reference Device
K192596, uLab Systems Dental aligner by uLab Systems Inc.

Indication for Use:
The CREOKORREKT 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:
CREOKORREKT Aligners consist of a series of dentist-prescribed, thin, clear, thermoformed polyurethane and copolyester orthodontic appliances. The aligners provide gentle continuous force to move the patient's teeth in small increments from their original positions to planned positions. CREOKORREKT Aligners are intended as an alternative to conventional wire and bracket orthodontic technology and fixed appliances for the treatment of patients with tooth malocclusion.

A dentist determines a treatment plan based on the assessment of the patient's teeth and prescribes the CREOKORREKT. To obtain the dimensions and details of a patient's dentition, a dentist takes intraoral

scanning or a physical impression (PVS Impression) and sends them with a prescription to CreoDent Prosthetics LTD.

With PVS impressions, physical models are fabricated and scanned. Scanned data are directly imported into dental design software for planning. CreoDent Prosthetics LTD designs the process of treatment by creating a series of the sequential model intended to gradually move the patient's teeth to the desired position in accordance with the dentist's prescription utilizing the dental design software. The doctor reviews and approves the treatment scheme. CreoDent Prosthetics LTD fabricates a series of models for thermoforming.

Summary of Technology Characteristics

The subject device is substantially equivalent to the current cleared devices. Comparison demonstrating Substantial Equivalence follows:

	Subject Device	**Primary Predicate**	**Reference Device**
Device Name	CREOKORREKT	Argen Clear Aligner	uLab Systems Dental aligner
510(k) Number	K211427	K192846	K192596
Manufacturer	CreoDent Prosthetics LTD	Argen Corporation	uLab Systems Inc.
Classification Number	21 CFR 872.5470, Class II Orthodontic Plastic Bracket	21 CFR 872.5470, Class II Orthodontic Plastic Bracket	21 CFR 872.5470, Class II Orthodontic Plastic Bracket
Product Code	NXC	NXC	NXC
Indications for Use	The CREOKORREKT 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 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.	The uLab Systems Dental Aligner is indicated for the alignment of permanent teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.
Mode of action	The appliance applies gentle forces on teeth according to the plan prescribed by the doctor.	The appliance applies gentle forces on teeth according to the plan prescribed by the doctor.	Orthodontic movement occurs through continuous gentle forces applied to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.
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.	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.	A series of custom-made removable clear plastic orthodontic aligners that sequentially position teeth by way of continuous gentle force.
Material	Zendura A (thin thermoformed polyurethane) or Zendura FLX (copolyester and polyurethane composite)	Thermoplastic polyurethane polyester composite resin	Zendura A (thin thermoformed polyurethane) or Zendura FLX (copolyester and polyurethane composite)

Manufacturing processes	- Scanning - Treatment planning - aligner model by 3D printer - pressure molding by heating machine - laser engraving	- Scanning - Treatment planning - aligner model by 3D printer - pressure molding by heating machine	- Scanning - Treatment planning - aligner model by 3D printer - pressure molding by heating machine
Thickness of material	0.76mm	-	-
Color of material	Clear	Clear	Clear
Software used for treatment planning/manufacture	Ortho System ™; 3Shape A/S (K180941) Autolign; Diorco (K192847)	Ortho System ™; 3Shape A/S (K180941)	uDesign; uLab Systems Inc. (K171295)
Prescription Use	Rx	Rx	Rx
Biocompatibility	Yes, shown to meet requirements of ISO 10993	Yes, shown to meet requirements	Yes, shown to meet requirements of ISO 10993

SE Discussion

The subject device and primary predicate, K192846 have same indications for Use, mode of action, description of use, thermoformed copolyester and polyurethane composite material (Zendura FLX), manufacturing process (i.e., Scanning, Treatment planning, 3D printing, Thermoforming, etc.), thickness of material, color of material, and treatment planning software.
The differences between the subject device and primary predicate are the material (Zendura A) and using software (Autolign: Diorco). To support the discrepancy of the different material, K192596 was added as the reference device for the substantial equivalence.
Zendura FLX and Zendura A have been produced in only one film format for each. The film is 0.76mm in thickness. Bay Materials, LLC supplies sheets in different widths and lengths or diameters but all of these are cut from the same film. Therefore, the material of the subject device is identical to that of the predicate devices.
To support the discrepancy of the different software used, a manufacturing process validation test was performed and it showed that no significant differences were found between the designs using Autolign (Diorco, K192847) and Ortho Analyzer (3shape, K180941)

Non-Clinical Testing

Non-clinical testing data are submitted to demonstrate substantial equivalence.

- Physical properties testing of the material (Zendura FLX and Zendura A) according to ASTM D6387, ASTM D790, ASTM D570 and ASTM D5420
- Biocompatibility Testing of the material (Zendura FLX and Zendura A) according to ISO 10993-3,5,10, and 11

Manufacturing Process Validation Testing

This test was conducted to validate the manufacturing process of the final product. It evaluated the fit, form, and function of the final product by a trained physician as compared to software treatment design. This test has met the pre-established acceptance criteria. The test results showed that the manufacturing process of the subject aligner achieves its intended use, and it is substantially equivalent to the predicate devices.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, CreoDent Prosthetics LTD concludes that the CREOKORREKT aligner is substantially equivalent to the predicate devices as herein.