510(k) Summary

K180648

Park Dental Research Aligners

Park Dental Research Corporation

Trade Name: Park Dental Research Aligners

Common Name: Sequential Aligner

Date of Preparation: November 28, 2018

Submitter: Dr. Ronald A Bulard

Submitter's Address: 2401 N. Commerce St. Suite E Ardmore, OK 73401

Submitter's Phone: 800-243-7372

Product Code: NXC

Regulation No.: 872.5470 Orthodontic Plastic Bracket

Classification: Class II

Predicate 510k: K113618 ClearCorrect System from ClearCorrect LLC

Device Description:

The Park Dental Research Aligners device is fabricated of clear thin thermoformed polyurethane plastic in a 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.

Indications for Use:

Park Dental Research Aligners are indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). Park Dental Research Aligners positions teeth by way of continuous gentle force.

The indications for use is highly similar to that of the predicate device, ClearCorrect, with the differences due to including the device name.

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.

Non-Clinical Performance Testing:

The material used for the Park Dental Research aligners is the same polyurethane material as used in the predicate device ClearCorrect System. It is called Zendura. A biocompatibility assessment determined no testing was needed since the material is the same as the predicate device. Park Dental Research conducted manufacturing validation with software to be used to fabricate the aligners and based upon the predetermined treatment plan.

Predicate Device Comparison Table

	Park Dental Research Aligners K180648	ClearCorrect System from ClearCorrect K113618
Regulation Number	21 CFR 872.5470	21 CFR 872.5470
Device Classification Name/Device Common Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket
Product Code	NXC	NXC
Classification	II	II
Indications for use	Park Dental Research Aligners are indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). Park Dental Research Aligners positions teeth by way of continuous gentle force.	The ClearCorrect System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The ClearCorrect System positions teeth by way of continuous gentle force.
Mode of action	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.	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.
Material	Zendura polyurethane	Zendura polyurethane

Conclusion:

Based on technological characteristics, mechanism of action, materials, indications for use and the results of non-clinical performance testing, Park Dental Research Aligners are substantially equivalent to ClearCorrect K113618.

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)*
K180648

Device Name
Park Dental Research Aligners

Indications for Use *(Describe)*
Park Dental Research Aligners are indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). Park Dental Research Aligners 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Park Dental Research Corporation
% Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030-0172

January 8, 2019

Re: K180648
Trade/Device Name: Park Dental Research Aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: November 29, 2018
Received: December 10, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2019.01.08 08:40:36 -05'00'

forTina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure