DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

ClearPath Orthodontics Ltd
c/o Patsy J Trisler, JD, RAC
Qserve Group US, Inc.
5600 Wisconsin Avenue
#509
Chevy Chase, Maryland 20815

July 6, 2017

Re: K162609
Trade/Device Name: ClearPath Aligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: May 30, 2017
Received: May 30, 2017

Dear Patsy J Trisler, JD, RAC:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mary S. Runner -A

Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Change Control Table, Change History

Change Control Table

Version	Document Author	Document Approver	Date Approved
1.00	Name, Title, Office	Name, Title, Office	MM/DD/YYYY

Complete Change Control Table (all versions) retained in SWIFT Docs.

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)*
K162609

Device Name

ClearPath Aligner

Indications for Use *(Describe)*

The ClearPath Aligner is a series of clear, lightweight, plastic appliances indicated for the correction of dental malocclusion in patients with permanent dentition (i.e. all second molars). The ClearPath Aligner 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.

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510(k) Summary – K162609

Submitter Name:	ClearPath Orthodontics Ltd
Submitter Address:	6-N, Main Boulevard, Johar Town, Lahore-Pakistan
Phone Number:	+92 42 111 333 276
Contact Person:	Dr. Waqas Wahab, Chief Executive Officer
Date Prepared:	19 September 2016; updated 5 July 2017
Device Trade Name:	ClearPath Aligner
Common Name	Clear Braces
Classification Name Number Product Code Regulatory Class	Orthodontic Plastic Bracket 21 CFR 872.5470 NXC 2
Predicate Device: Reference Device:	K123514 ClearPath Aligner, ClearPath Orthodontics No reference devices were included
Statement of Intended Use	The ClearPath Aligner is a series of clear, lightweight, plastic appliances indicated for the correction of dental malocclusion in patients with permanent dentition (i.e. all second molars). The ClearPath Aligner is intended to position teeth by way of continuous gentle force.
Device Description	ClearPath Orthodontics uses clear, thin, thermoformed plastic material for the manufacture of its ClearPath Aligner. The aligners are provided non-sterile and are customized for each patient according to the molds provided by the treating dentist or orthodontist. Depending on the patient need and the treatment plan, a series of aligners may be used. The duration of use for each aligner is 14 days and it is to be worn except during meals.
Mechanism of Action	Each ClearPath Aligner exerts gentle force to achieve progressive realignment of the teeth until the final correction has been attained.
Summary of Technological Characteristics	ClearPath Orthodontics manufactures the customized aligners based on standard molds sent to the company by the prescribing dentist or orthodontist. The molds are made after the clinician has assessed the patient's teeth, designed a treatment plan, and taken the impressions. The plastic used for fabrication of the aligners is a commonly used thermoformed plastic, used in many dental appliances. It has a long history of safe and biocompatible use for this purpose.

Performance Testing

Bench/Animal Testing

No *in vitro* or animal testing were required for this product because the identical design and materials compared to the predicate device assure that the preformed aligners are capable of performing similarly to the predicate device for the specified intended use.

Clinical Evaluations

The reason for this 510(k) was to expand the indication to include realignment of all permanent teeth. The predicate ClearPath Aligner (K123514) is intended "for minor anterior tooth movement".

Clinical case reports were submitted in the 510(k) to demonstrate that the aligners can effectively realign all permanent teeth as indicated.

Comparison to Predicate Device:

The ClearPath Aligner is identical to the predicate device. The difference is the original ClearPath Aligner (predicate) had the indication, as noted, that was limited to anterior tooth movement. The data submitted in the 510(k) support the broader indications for use.

Substantial Equivalence Conclusion

Thus, based on:

- the same intended use,
- the same design,
- identical materials,
- identical methods used for fabricating the aligners, and
- submission of clinical reports that demonstrate the device performs as intended,

it can be concluded that the ClearPath Aligner is substantially equivalent to the predicate device.