K123514

510(k) Summary

Submitter Name:	ClearPath Orthodontics
Submitter Address:	54E/1, D/1, Gulberg III, Lahore, Pakistan, 54000
Phone Number:	00 92 42 35752012
Contact Person:	Dr. Waqas Wahab
Date Prepared:	09 November 2012; Revised 24 October 2013
Device Trade Name:	ClearPath Aligner
Common Name	Clear Braces
Classification Name, Number & Product Code:	Orthodontic Plastic Bracket 21 CFR 872.5470 NXC
Predicate Devices:	K073121 – NuBrace Invisible Removable Orthodontics (IRO), NuBrace, Inc. K981095 – Align System, Align Technology Inc.
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 for minor anterior tooth movement 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/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.

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Performance Testing	No bench testing was warranted for this product because the scientific literature and similarity in design, materials and use to the predicate devices assure that the preformed aligners are safe and effective for the specified intended use.
Comparison to the Predicate Devices	The ClearPath Aligner was compared to the two predicate devices with respect to indications for use, design, material composition, and the mechanism of action (gentle continuous pressure on teeth).
Substantial Equivalence Conclusion	Based upon the same intended use compared to the predicates, the similar base materials used for fabricating the aligners, the same basic design, and the same mechanism of action, it can be concluded that the ClearPath Aligner is substantially equivalent to the predicate devices.
Verifications regarding this 510(k) Summary	The summary includes only information that is also covered in the body of the 510(k). The summary does not contain any puffery or unsubstantiated labeling claims. The summary does not contain any raw data, i.e., contains only summary data. The summary does not contain any trade secret or confidential commercial information. The summary does not contain any patient identification information.

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

November 1, 2013

ClearPath Orthodontics
C/O Ms. Patsy J. Trisler, J.D., RAC
Vice President, Regulatory and Clinical Affairs
Qserve America, Incorporated
154 Main Street, Suite 2
CHARLESTOWN NH 03603

Re: K123514
Trade/Device Name: ClearPath Aligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NXC
Dated: October 24, 2013
Received: October 30, 2013

Dear Ms. Trisler:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K123514

Device Name: **ClearPath Aligner**

Indications For 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 for minor anterior tooth movement by way of continuous gentle force.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
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