005_510 (k) Summary

This summary of 510(k) is being submitted in accordance with the requirements of 21 C.F.R. 807.92.

1. **Date Summary Prepared:** April 14, 2019

2. **Submitter Information:**

Name	Shandong Huge Dental Material Corporation
Address	No. 68 Shanhai Road, Donggang District, Rizhao City, Shandong Province, 276800, P. R. China
Telephone	+86 633 2277285
Fax	+86 633 2277298
Contact	Ms. Maggie Zheng
E-mail	zhengxy@hugedent.com

3. **Device Name:**

Trade name: Orthodontic Appliance

Common name: Aligner, Sequential

Classification name: Orthodontic plastic bracket

4. **Substantially Equivalent Device:**

Table 2: Predicate Device Information

Company Name	Device Name	510 (k) NO.	Substantially Equivalent (SESE) Decision Date
ClearPath Orthodontics Ltd	ClearPath Aligner	K162609	09/19/2016

No reference devices were used in this submission.

5. **Description of Device:**

The Orthodontic Appliance is a series of clear, lightweight, plastic aligners that are used to replace traditional orthodontic wires and brackets for the alignment of maloccluded or misaligned teeth. This series of aligners moves the teeth gently, and in small increments, from their original to their final treated position for improved dental alignment. The product is made of a polymer thermoplastic material (polyvinyl ester mixture) by pressing.

The doctor-prescribed Orthodontic Appliance are provided non-sterile and are customized for each patient according to the 3D printed data designed by Clear Aligner Design Software. Shandong Huge Dental Material Corporation manufactures the Orthodontic Appliance by thermoforming commercially available thermoplastic material and send them to the clinician. The clinician confirms the fit of the aligners upon delivery to the patient and monitors the patient's progress throughout treatment. Depending on the patient need and the treatment plan, a series of aligners may be used. The duration of use for each pair of appliance is 2-3 weeks, wear the appliances for at least 20 hours every day and it is to be worn except during eating or cleaning of the oral cavity.

The type of Orthodontic Appliance is LX-A with various thickness so that the clinician can select suitable thickness based on patients' teeth micromaxillary deformity conditions. Different thickness are identical in chemical compositions, indications for use, functions, performance characteristics, operation principle and other aspects.

6. Intended for Use / including the indications for use:

The Orthodontic Appliance is indicated for the correction of tooth malocclusion in patients with permanent dentition. The Orthodontic Appliance moves the teeth by continuous gentle force.

7. Mechanism of Action:

The mechanism of action is similar to the predicate device and supports a determination of substantial equivalence. Orthodontic tooth movement occurs through continuous gentle force applied to the teeth by the appliance based on a healthcare practitioner's prescription.

8. Technological Characteristics:

Treatment of tooth malocclusions via a series of plastic appliances that incrementally moves the teeth to a desired final position is the technological principle for both the subject device and the predicate device. A comparison of technological characteristics between the subject device and the predicate device has been performed. The results of this comparison demonstrate that the indications for use, design, technological characteristics, mechanism of action, performance, materials and biocompatibility are substantially equivalent.

Table 3: Device Comparison Table

Comparison Items	**Subject Device**	**Predicate Device**
Device Name	Orthodontic Appliance	ClearPath Aligner
510 (k) Number	To be determined	K162609
Regulation Number	21 C.F.R. 872.5470	21 C.F.R. 872.5470
Product Code	NXC	NXC
Classifications	Class II	Class II
Indications for use	The Orthodontic Appliance is indicated for the correction of tooth malocclusion in patients with permanent dentition. The Orthodontic Appliance moves the teeth by continuous gentle force.	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.
Material	Thermoplastic material	Thermoplastic material
Mechanism of Action	Continuous gentle force applied to teeth to achieve movement.	Continuous gentle force applied to teeth to achieve movement.
Manufacturing method	Thermoforming.	Thermoforming.
Conditions of Use	The duration of use for each pair of appliance is 2-3 weeks, wear the appliances for at least 20 hours every day and it is to be worn except during eating or cleaning of the oral cavity.	The duration of use for each pair of appliance is 2-3 weeks, wear the appliances for at least 20 hours every day and it is to be worn except during eating or cleaning of the oral cavity.

Table 3: Device Comparison Table

Comparison Items	Subject Device	Predicate Device
Device Name	Orthodontic Appliance	ClearPath Aligner
510 (k) Number	To be determined	K162609
	The treatment plan varies by individual patient prescription.	The treatment plan varies by individual patient prescription.
Biocompatibility	Biocompatible	Biocompatible
Sterility	Non-sterile	Non-sterile
Anatomical Site	Used by dentist or orthodontist on teeth for dental patients.	Used by dentist or orthodontist on teeth for dental patients.

9. Summary of Non-Clinical Performance Testing:

There is no international/national/industrial standards regarding the performance of this product. The performance testing for the subject device was performed and showed that the subject device meets all internal final inspection standard, while the physical and mechanical properties as well as the biocompability of the thermoplastic materials used to fabricate the aligners have previously been demonstrated by the manufacturer of the base materials.

The test items include appearance and surface characteristics, dimensions, pH value, elasticity variable, volume weight, water sorption, solubility. Meanwhile, the comparative testing was conducted between the proposed and the predicate device to determine substantial equivalence.

10. Summary of Biocompatibility:

The thermoplastic material used for fabrication of the aligners is commonly used in many dental appliances, which has a long history of safe and biocompatible use for this purpose. And there is sufficient information from the predicate device to demonstrate that this product provide reasonable assurance of safety and effectiveness. The formulation of the subject device does not contain any new or non-conventional chemicals compared to the legally marketed predicate device.

Biocompatibility tests were performed to satisfied the ISO 10993 standards. The test results of

the tests met the requirements of the study protocols, the tests including Cytotoxicity (ISO 10993-5), Skin Sensitization (ISO 10993-10), Intracutaneous Reactivity (ISO 10993-10), Subchronic systemic toxicity (ISO 10993-11) and Genotoxicity (ISO 10993-3).

11. Summary of Clinical Performance Data:

The performance of Orthodontic Appliance in the clinical environment has been well established since the first such devices were cleared by the FDA in 1998 under product code NXC. Therefore, there was no clinical testing required to support Orthodontic Appliance, as the indications for use is equivalent to the predicate device.

The substantial equivalence of the subject device to the ClearPath Aligner is supported by the non-clinical testing that was performed, along with other supporting documentation, and presented in this submission.

12. Software Verification and Validation Testing

Software verification and validation testing were conducted on the software that facilitates ordering and processing of the Orthodontic Appliance to support that the device is as safe and effective as the predicates. Documentation was provided as recommended by FDA' s Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software for this device was considered as a "moderate" level of concern.

13. Summary of Substantial Equivalence

The subject device, Orthodontic Appliance, has substantially equivalent Indications for Use as the identified predicate device. While the verbiage of the Indications of Use of the subject device is minor different than the declared predicate device; however, these minor differences are not of significance and do not alter the intended therapeutic use of the device as compared to the predicate device.

The conclusions drawn from the data included in this submission, demonstrates that the subject

device, Orthodontic Appliance, is substantially equivalent to the predicate device in indications for use, design, technological characteristics, mechanism of action, performance, materials and biocompatibility.

14. Photo of the device