510(k) SUMMARY
K173784

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Proprietary Name: Smylio Invisible Clear Aligners

Common Name: Orthodontic Plastic Brackets

Product Code: NXC – Orthodontic Plastic Brackets

Device Classification: Class II, 21 CFR 872.5470

Primary Predicate Device: Derby Dental Laboratory Custom Clear Aligner System (K173785)

Reference Predicates: 3Shape OrthoSystem™ Software (K152086)
ClearCorrect System (K113618)

Device Description:

The Smylio Invisible Clear Aligners are intraoral thermoformed plastic aligners that are worn 20 to 22 hours per day and are designed to be used in a sequence, each aligner providing a gentle continuous force, to allow for the movement of teeth to the final desired position. The aligners are to be removed for eating and for cleaning.

Smylio Invisible Clear Aligners are fabricated using a three-step process.

The first step is to obtain the dimensions and details of the patient's baseline dentition. This is generally done using an oral scan data or a physical impression. This scanned data (digital CAD/CAM models or patient models) are imported into specialized dental software for treatment planning.

The second step is the printing of 3D models of the treatment plan for use in step 3 (thermoforming). In the second step, the doctor utilizes a software application to plan the treatment by creating a series of sequential models that gradually position the teeth into their final desired position. A 3D printer is used to create the molds needed for each treatment step to provide the surface around which the aligner is thermoformed.

The final step is the thermoforming of a plastic sheet material to each of the sequential treatment steps. This process is done using a standard thermoforming equipment and the appropriate material as outlined in this submission.

Software Description

Specialized orthodontic CAD/CAM software will be used to develop the treatment plans and to produce standard 3D printer files that will facilitate the manufacturing of each sequential aligner in the treatment plan. The software application used for the manufacturing validation in this submission is the 3Shape®.

Material:

The material used for the manufacturing validation in this submission is the Zendura®.

Indications for Use:

The Smylio Invisible Clear Aligners is indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.

Comparison to Predicate Devices:

Table 1: Functional Specification Comparison

Functional Specification	***Smylio Invisible Clear Aligners***	***Custom Clear Aligner System (K173785)***
Material	Co-polyester or Co-Polymer	Co-polyester or Co-Polymer
Mode of Action	Continuous gentle force applied to teeth to achieve movement	Continuous gentle force applied to teeth to achieve movement
Features:		
Device Description	Sequential thermoformed plastic aligners	Sequential thermoformed plastic aligners
Patient Removable?	Yes	Yes
Duration of Use	20 to 22 hours per day	20 to 22 hours per day
Indication for Use	The Smylio Invisible Clear Aligners is indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.	The Custom Clear Aligner is indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.

Comparison of Indications for Use to Predicate Devices:

Based on the above comparison, the indications for use of the Smylio Invisible Clear Aligners is similar to that of the Derby Dental Custom Clear Aligner (K173785).

Comparison of Technological Characteristics to Predicate Devices:

Based on the above comparison, the design and construction of the Smylio Invisible Clear Aligners is similar to that of the Derby Dental Custom Clear Aligner (K173785).

Non-clinical performance testing:

Manufacturing Validation

A manufacturing validation was performed to demonstrate the dimensional accuracy of the manufacturing process for Smylio Aligners. Three critical aspects of the manufacturing process were assessed for accuracy: digital dentition models from treatment planning, 3D printed molds, and the final thermoformed aligners.

An independent 3rd party software and digital calipers were used to perform point-to-point and critical displacement measurements.

All translational measurements were within 0.3 mm of the target input value and all rotational measurements were within 3° of the target input value, the predefined tolerance of the manufacturing process. There were no statistical differences in the difference in the intended and measured values observed from any of the groups. This test has met the pre-established acceptance criteria to demonstrate dimensional accuracy.

Biocompatibility

A biocompatibility assessment was conducted. The Smylio Invisible Clear Aligners have been tested and shown to be compliant with the following standards:

- ISO 7405:2008 – Dentistry – Evaluation of biocompatibility of medical devices used in dentistry

Clinical performance testing:

Clinical performance testing was not conducted.

Conclusion:

Based on comparison of indications for use, technological characteristics, performance testing, biocompatibility assessment, we believe that Smylio Invisible Clear Aligners are substantially equivalent to the predicate devices.