June 27, 2019

DynaFlex
Matthew Malabey
Quality & Regulatory Director
10403 International Plaza Dr.
St. Ann, Missouri 63074

Re: K190583
Trade/Device Name: DynaFlex
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: March 25, 2019
Received: March 25, 2019

Dear Matthew Malabey:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Srinivas Nandkumar, Ph.D.
Acting Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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)*
K190583

Device Name
DynaFlex® Clear Aligner

Indications for Use *(Describe)*

DynaFlex® Clear Aligner is a series of clear, lightweight, plastic retainers indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion in patients by moving teeth progressively to a final, treated state.

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.

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510(k) Summary (K190583)

Submitter:

DynaFlex
10403 International Plaza Dr.
St. Ann, MO 63074

Contact:

Matthew Malabey
Quality & Regulatory
DynaFlex
314-426-4020– Phone
314-429-7575– Fax

Date Summary Prepared: June 26, 2019

Device Name:

- Trade Name – DynaFlex Clear Aligner
- Classification name – Sequential Aligner
- Regulation Description – Orthodontic plastic bracket
- Definition – The device moves by gentle force for treatment of minor tooth malocclusion
- Regulation Medical Specialty – Dental
- Review Panel – Dental
- Product Code – NXC
- Regulation Number 21 CFR§ 872.5470
- Device Class – 2

Devices for Which Substantial Equivalence is Claimed:

- **Primary Predicate:** Specialty Appliance Works, Inc.– Clear Image™ Aligner (K071970)
- **Reference Device:** Clear Correct, Inc.– Clear Correct (K082556)

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Device Description:

DynaFlex ® Clear Aligner Appliance is a series of clear, lightweight, plastic retainers indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion in patients by moving teeth progressively to a final, treated state.

The device will be patient-specific and will be sold by prescription. The device is manufactured with medical grade thermo plastic that is standard throughout the industry.

Aligners are fabricated from .030 thermoformed plastic. The mechanism of force application to the teeth is via intentional distortion of the plastic as the aligners are seated in the mouth. Each subsequent aligner in the overall progressive series is made from a mold of the patient's teeth which reflect subtle changes in the position of the teeth from the previous aligner. The positional changes are introduced into each aligner in the laboratory by moving the teeth on the construction model and then forming the aligner on the same model. The overall treatment is prescribed by the dentist to the laboratory where they are fabricated.

Aligners may be adjusted by the dentist. Aligners are completely removable by the patient and treatment may be discontinued at any time. The appliance if provided as a non-sterile device and single use.

Indications for Use:

DynaFlex ® Clear Aligner Appliance is a series of clear, lightweight, plastic retainers indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion in patients by moving teeth progressively to a final, treated state. DynaFlex Clear Aligner is for prescription only.

Summary of Technological Characteristics:

Section 5.0: 510(k) Summary Submitter: DynaFlex® Clear Aligner Premarket Notification: Traditional 510(k): A dental health care professional (e.g. Orthodontist or Technological dentist), prescribes the Clear Aligner system based on an characteristics assessment of the patient's teeth, determines a course of treatment with the system, takes molds of the patient's teeth, and completes a prescription form. The molds and prescription are sent to Dynaflex. DynaFlex designs a series of plastic trays intended to gradually realign the patient's teeth in accordance with the physician's prescription. DynaFlex produces the trays, which are fabricated from .030 thermoformed plastic. The mechanism of force application to the teeth is via intentional distortion of the plastic as the aligners are seated in the mouth. Each subsequent aligner in the overall progressive series is made from a mold of the patient's teeth which reflect subtle changes in the position of the teeth from the previous aligner. The positional changes are introduced into each aligner in the laboratory by moving the teeth on the construction model and then forming the aligner on the model. The overall treatment is prescribed by the dentist to the

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laboratory where they are fabricated. This technology is essentially identical to that used by a number of sequential alignment systems, including the predicates referenced above.

Performance Characteristics:

Bench testing of the Aligners has not been performed; however, there is sufficient information available from the scientific literature & other legally FDA cleared device of similar characteristics and material to demonstrate that the preformed aligner provides reasonable assurance of effectiveness.

Non-Clinical Performance Testing

As part of demonstrating substantial equivalence to the predicate devices that are subject to this 510(k) submission, DynaFlex completed a number of non-clinical performance tests. The DynaFlex Clear Aligner meets all the requirements for overall design, biocompatibility, and performance results confirming that the design output meets the design inputs and specifications for the device.

The DynaFlex Clear Aligner passed all the testing in accordance with internal requirements, national standards, and international standards to support substantial equivalence of the subject device.

Manufacturing Process Flow validation was performed to ensure that the finished device matches the specification of the doctors' requirements. The output and work model and aligner were tested and compared. DynaFlex Clear Aligners met the specifications of this testing.

DynaFlex has completed biocompatibility testing per ISO 10993-1 and its applicable parts, as appropriate for the aligner contact and duration. The mechanical properties of the thermoformed plastic has been previously demonstrated by the manufacturer as appropriate for use with aligners, therefore no additional testing was required to demonstrate substantial equivalence.

Substantial Equivalence:

DynaFlex® Clear Aligner is substantially equivalent to other FDA approved legally marketed orthodontic devices in the United States. *DynaFlex Clear Aligner Aligners* is used in a manner similar to the *Clear Image*™ system (Primary Predicate) marketed by Specialty Appliance Works, Inc., and *Clear Correct* marketed by Clear Correct, Inc. (Reference Device) The proposed and predicate devices are of similar design; made from virtually identical materials, and are fabricated using similar manufacturing methods that are common to the dental device industry. Furthermore, DynaFlex® Clear Aligner Appliance have the same intended uses as the predicate devices in that they serve as an oral appliance constructed of polymer components that when fabricated into their final form and dimensions, are a dental appliance that are custom fit for the patient. The properties and characteristics of the predicate devices are compared to DynaFlex® Clear Aligner Devices in the Table 12-1.

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Table 12-1
Substantial Equivalence Comparison

Manufacturer:	**DynaFlex®**	**Specialty Appliances Works, Inc. (Primary Predicate)**	**ClearCorrect, Inc. (Reference Device)**	**Comparison**
Trade Name:	*DynaFlex® Clear Aligner*	*Clear Image™Aligners*	*ClearCorrect™*	*N/A*
Product Images:				N/A
Product Code:	NXC	NXC	NXC	*Same*
Attach Mechanism: (lower to upper tray)	None	None	None	Same
Regulation Number:	872.5470	872.5470	872.5470	Same
Regulation Name:	Orthodontic plastic bracket	Orthodontic plastic bracket	Orthodontic plastic bracket	Same
510(k):	K190583	K071970	K082556	N/A
Indications for Use:	*DynaFlex ® Clear Aligner Appliance is a series of clear, lightweight, plastic retainers indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion in patients by moving teeth progressively to a final, treated state. DynaFlex Clear Aligner is for prescription only.*	Specialty Appliances' Clear ImageTM Aligners primarily are directed toward treating a patient's anterior teeth. Such treatment involves the relatively minor orthodontic tooth movements intended to impact a patient's appearance and self image. The Dentist makes final decision and adjustment per treatment plan	The CearCorrect 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. The Dentist makes final decision and adjustment per treatment plan	Same
Mechanism of Action:	Basic mechanics follows the same principles of conventional orthodontics. The aligners apply a simple force on the tooth. Therefore, the Sequential aligners can produce tipping, rotation, extrusion and intrusion forces. However, the extrusive force from the Sequential Retainers is limited.	Basic mechanics follows the same principles of conventional orthodontics. The aligners apply a simple force on the tooth. Therefore, the Sequential aligners can produce tipping, rotation, extrusion and intrusion forces. However, the extrusive	Basic mechanics follows the same principles of conventional orthodontics. The aligners apply a simple force on the tooth. Therefore, the Sequential aligners can produce tipping, rotation, extrusion and intrusion forces. However, the extrusive force from the Sequential Retainers is limited.	Same

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		force from the Sequential Retainers is limited.		
Materials:				
Stainless Steel:	None	None	None	Same
Dental Plastic:	Thermoformed (Plastic)	Thermoformed (Plastic)	Thermoformed (Plastic)	Same
Dimensions:	Various (see Engineering Drawings)	Various (Not available)	Various (Not available)	Same
Supplied Sterile:	No	No	No	Same
Single Use:	Yes (i.e., multiple use by the same patient)	Yes (i.e., multiple use by the same patient)	Yes (i.e., multiple use by the same patient)	Same
Worn at Night:	Yes	Yes	Yes	Same
Patient Population	Patient with Permanent Dentition	Patient with Permanent Dentition	Patient with Permanent Dentition	Same
Physical Properties	Plastic Sheets/Proprietary	Plastic Sheets/Proprietary	Plastic Sheets/Proprietary	Same
Biocompatibility	Passed ISO 10993-1 and series	Passed ISO 10993-1 and series	Passed ISO 10993-1 and series	Same
Size	Patient specific	Patient specific	Patient specific	Same
Material	0.03” Thermoplastic	0.03” Thermoplastic	0.03” Thermoplastic	Same
Healthcare Professional Review	The dental practitioner reviews aligner series prior to fabrication and has the option to reject or request modifications to the setup prior to approving it for aligner fabrication.	The dental practitioner reviews aligner series prior to fabrication and has the option to reject or request modifications to the setup prior to approving it for aligner fabrication.	The dental practitioner reviews aligner series prior to fabrication and has the option to reject or request modifications to the setup prior to approving it for aligner fabrication.	Same

Substantial Equivalence Conclusion

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Based on the comparison and analysis above, the DynaFlex Clear Aligner is determined to be substantially equivalent to the referenced predicate device(s).