June 5, 2023

Dyna Flex
Matthew Malabey
Director of Operations
8050 Hawk Ridge Trail
Lake Saint Louis, Missouri 63367

Re: K230225
Trade/Device Name: DynaFlex Clear Brackets & Buttons
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NJM
Dated: February 21, 2023
Received: February 21, 2023

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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
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OHT1: Office of Ophthalmic, Anesthesia,
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Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230225

Device Name
DynaFlex Clear Brackets & Buttons

Indications for Use *(Describe)*
DynaFlex ® Clear Bracket & Buttons is indicated for alignment of teeth during orthodontic treatment.

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 (K230225)

Submitter:

DynaFlex
8050 Hawk Ridge Trail.
Lake St. Louis, MO 63367

Contact:

Matthew Malabey
Director of Operations
DynaFlex
314-426-4020– Phone
314-429-7575– Fax

Date Summary Prepared: June 1st, 2023

Device Name:

- Trade Name – DynaFlex Clear Brackets & Buttons
- Classification name – Orthodontic Plastic Bracket
- Regulation Medical Specialty – Dental
- Review Panel – Dental
- Product Code – NJM
- Regulation Number 21 CFR§ 872.5470
- Device Class – 2

Devices for Which Substantial Equivalence is Claimed:

- **Primary Predicate:** Ortho Organizers (Henry Schein).– Carriere SLX 3D Clear (K173440)

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Device Description:

DynaFlex ® Clear Brackets & Buttons is a series of clear, lightweight, ceramic brackets, and buttons. DynaFlex ® Clear Brackets & Buttons are used in the alignment of teeth through orthodontic treatment of misalignment and malocclusion in patients by moving teeth progressively to a final, treated state.

DynaFlex ® Clear Brackets & Buttons are designed to move teeth to improve their alignment. Ceramic brackets are bonded to natural teeth by dental professionals to connect with orthodontic wires to cause tooth movement to a more preferred position. Ceramic brackets are intended for use in affixed to a tooth so that pressure can be exerted on the teeth. Bonding supplies are used to bond the bracket on to a tooth. Ceramic brackets are bonded to natural teeth by dental professionals to connect with orthodontic wires to cause tooth movement to a more preferred position.

DynaFlex ® Clear Brackets & Buttons may be adjusted by the dentist. The appliance is provided as a non-sterile device and is single use. DynaFlex® Clear Brackets & Buttons is for prescription only.

Indications for Use:

DynaFlex ® Clear Bracket & Buttons is indicated for alignment of teeth during orthodontic treatment.

Summary of Technological Characteristics:

A dental health care professional (e.g. Orthodontist or dentist), prescribes the Clear Brackets & Buttons based on an characteristics assessment of the patient's teeth, determines a course of treatment with the system. DynaFlex Clear Brackets and Buttons all have a bracket body made of ceramic. DynaFlex brackets are self-ligating ceramic door with a nickel-titanium spring mechanism. Orthodontic brackets are affixed to teeth using an orthodontic adhesive. Pressure is exerted on a tooth when the brackets are used in combination with archwires and/or other intraoral modules. The pressure causes tooth movement.

Performance Characteristics:

Bench testing of the clear brackets & buttons was performed. Specifically, bond strength testing was performed to determine the amount of force required to separate the bonded bracket from the tooth. The minimum specification for bond strength was met by all samples tested.

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 Bracket & Buttons meet all the requirements for overall design,

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biocompatibility, and performance results confirming that the design output meets the design inputs and specifications for the device.

The DynaFlex Clear brackets & buttons meet 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 technical requirements. The output and specifications were tested and compared. DynaFlex Clear Bracket & Buttons met the specifications of this testing.

DynaFlex has completed biocompatibility testing per ISO 10993-1 and its applicable parts, as appropriate for the Clear Bracket & Buttons contact and duration. The mechanical properties of the clear brackets and buttons have been demonstrated by the manufacturer as appropriate for use with clear brackets.

Substantial Equivalence:

DynaFlex® Clear brackets & buttons is substantially equivalent to the Carriere SLX 3D (Clear Kl 7 3 440). *DynaFlex Clear Bracket & Buttons* is used in a manner similar to the *Carriere SLX 3D Clear (K173440)* system (Primary Predicate) marketed by Ortho Organizers (Henry Schein).The proposed and predicate devices are of similar design; made from similar materials and are fabricated using similar manufacturing methods that are common to the dental device industry.

Furthermore, DynaFlex® Clear Bracket & Buttons have similar intended uses as the predicate devices. Both the predicate and the subject device serve as an oral appliance constructed of same polymer components, which are intended to move teeth.

There are no substantial technical or functional differences between the predicated orthodontic ceramic bracket and the predicate device in terms of design, function, safety and intended use. Both are ceramic.

However, the self-ligating brackets made of polycrystalline alumina in the proposed device are made with nickel-titanium springs, unlike the stainless-steel springs of the Predicate Device (K173440). Nickel titanium springs in the proposed device can be considered substantially equivalent to the predicate device, as this material presents no additional risks – technologically, biologically, and clinically. Therefore, there are no substantial differences between the subject device and predicate device in terms of the spring used.

The properties and characteristics of the predicate devices are compared to DynaFlex● Clear Bracket & Buttons in the Table 5-1.

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Table 5-1
Substantial Equivalence Comparison

Manufacturer:	DynaFlex®	Ortho Organizer (Henry Schein Co, Predicate)	Comparison
Trade Name:	DynaFlex® Clear Brackets & Buttons	Carriere SLX 3D Clear	*N/A*
Product Images:			N/A
Product Code:	NJM	NJM	*Same*
Medical Specialty	Dental	Dental	Same
Regulation Number:	872.5470	872.5470	Same
Regulation Name:	Orthodontic plastic bracket	Orthodontic plastic bracket	Same
510(k):	K230225	K173440	N/A
Indications for Use:	DynaFlex ® Clear Bracket & Buttons is indicated for alignment of teeth during orthodontic treatment.	The Carriere SLX 3D Clear orthodontic ceramic bracket system is intended to aid in the movement of teeth during orthodontic treatment	Similar
Design	Archwire slot, tiewings for ligature and identification marks for placement Hooks for ligation, for additional tooth movement Molded ceramic body with rounded corners and e Slot to hold orthodontic wires edges	Archwire slot, tiewings for ligature and identification marks for placement Hooks for ligation, for additional tooth movement Molded ceramic body with rounded corners and e Slot to hold orthodontic wires edges	Same
Base:	Mechanical Lock Base	Mechanical Lock Base	Same
In/Out	.027" - .039"	.025" – .046"	Within range of predicate
Torque	-12° through + 12°	-17° through +17°	Within range of predicate
Angulation	Up to + 9°	Up to + 9°	Within range of predicate
Rotation	Up to + 5°	Up to + 12°	Within range of predicate
Mode of Use	An archwire (provided by clinician and worn by patient) is inserted into the device and provides the light orthodontic forces required to move teeth per the dental professional's technique and treatment goals.	An archwire (provided by clinician and worn by patient) is inserted into the device and provides the light orthodontic forces required to move teeth per the dental professional's technique and treatment goals.	Same
Application	Bonded with Orthodontic Adhesive	Bonded with Orthodontic Adhesive	Same
Minimum Bond Strength (N/MPa)	80/6.0	103.7/7.63	Within range of predicate
Supplied Sterile:	No	No	Same

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Single Use:	Yes	Yes	Same
Target Users	Dental Professionals trained in orthodontics	Dental Professionals trained in orthodontics	Same
Physical Properties	Polycrystalline Alumina / Nickle-Titanium Alloy	Polycrystalline Alumina / Stainless Steel	Similar
Biocompatibility	Passed ISO 10993-1 and series	Passed ISO 10993-1 and series	Same
Material	Polycrystalline (translucent) alumina,	Polycrystalline (translucent) alumina	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 Brackets & Buttons is determined to be substantially equivalent to the predicate device.