September 14, 2023

LightForce Orthodontics
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K232827
Trade/Device Name: LightForce Orthodontic System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NJM, PNN
Dated: September 13, 2023
Received: September 13, 2023

Dear Prithul Bom:

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
ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232827

Device Name
LightForce Orthodontic System

Indications for Use *(Describe)*
The LightForce Orthodontic System is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients using patient-matched orthodontic appliances.

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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5. 510(k) Summary

510(k) owner's name:	LightForce Orthodontics
Address:	44 Third Ave. Burlington, MA 01803
Phone number:	800-481-0185
Name of contact person:	Jeffrey Roberts
Date the summary was prepared:	August 25, 2023

Trade/Proprietary Name of Device:	LightForce Orthodontic System
Common or Usual Name:	Orthodontic Ceramic Bracket and Accessory
Classification Name:	Orthodontic Plastic Bracket
Classification Regulation:	21 CFR 872.5470
Product Code:	NJM, PNN
Regulatory Class:	II

Predicate Devices:

Primary Predicate: LightForce Orthodontic System (K222764)

Reference Predicate: Dentsply International IN-OVATION C brackets (K060837)

Device Description:

The LightForce Orthodontic System (LFO System) is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients using patient-matched orthodontic appliances. The LFO System consists of patient-specific ceramic brackets, patient-specific placement jigs, and TPS that allows the orthodontist to view, measure, and diagnose cases.

The patient-specific brackets are available with slot sizes to orthodontic wires up to 0.022” in height and come in a variety of hook options colors and shades. The patient-specific placement jig is an optional-use lab device to aid orthodontists in bracket placement and bonding and is composed of an FDA cleared, class 1 certification material. The LFO system does not contain commercially available or patient-specific shaped arch wires, ligatures, or adhesives that affix the brackets to the teeth. The LFO system packaging consists of a single product offering box with indirect bonding trays (IDB trays) loaded with brackets as well as a secondary set of individual brackets and, where applicable IDB trays and/or bite turbo indirect bonding trays. The LFO system may also include non-patient-specific brackets for temporary use with predetermined torque, tip, offset and base contour, packaged and labeled separately.

The inclusion of an optional self ligating metal clip is to ligate a wire to the bracket by encapsulating the wire in the slot of the bracket.

Intended Use:

The LFO System is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients using patient-matched orthodontic appliances.

The indications for use are the same as the primary predicate K222764.

Technological Characteristics:

The LFO System brackets, like its primary predicate LFO system (K222764), are composed of a polycrystalline alumina with a bracket design consisting of tie-wings for ligation, a primary archwire slot and auxiliary slots. There are rounded corners and edges along with a rounded hook on the distal-gingival tie wing to accommodate accessories during orthodontic treatment. These design features allow an archwire to move the bonded brackets along a designated path until the desired tooth position is achieved. The brackets have a mechanical locking base design and are built through additive manufacturing methods. The technological characteristics of the LFO System brackets differ from the predicate LFO system in that the updated LFO system offers the inclusion of an optional self ligating nitinol clip. The self ligating nitinol clip included in the LFO system has the same technological characteristics as the reference predicate Dentsply International IN-OVATION C brackets (K060837).

Non-clinical Performance Testing:

Non-clinical performance testing was performed to ensure that the LFO system brackets were similar to the predicate LFO System. Performance testing was carried out to evaluate the features of the design that were different/changed between the LFO system and its predicate. Performance testing consisted of:

1. Tie-wing fracture strength is the fracture strength of the tie-wing complex when a load is placed directly under the tie wing. The tie wing fracture strength of LFO System brackets is equivalent to the predicate device.
2. Wire friction force is the force required to drag a ligated stainless-steel wire through the primary slot of the bracket. The friction force of the LFO System brackets with the inclusion of self-ligating metal clips is substantially better (lower) than the predicate device.
3. Wire escapement testing is an evaluation of the self ligating clip and bracket's capability to successfully hold a wire in place when subjected to normal orthodontic forces. The LFO system’s metal clip is an effective mechanism, in combination with ceramic brackets, to retain a wire in a slot throughout treatment.

Clinical Performance Testing:

No clinical performance testing was conducted on LFO System brackets.

Biocompatibility:

A biocompatibility assessment was performed on the proposed modified LFO System to assess the impact of including the nitinol clip to the overall material biocompatibility per ISO 10993-1:2018 and the US FDA's guidance, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process." and ANSI/ADA Standard No. 41-2020 Evaluation of Biocompatibility of Medical Devices Used in Dentistry. LFO system brackets are considered mucosal membrane contacting for a duration of greater than 30 days.

The results of the evaluation met the requirements of the standards as identified above.

Substantial Equivalence:

Lightforce Orthodontics claims the LFO System is substantially equivalent to the legally marketed predicate device based on intended use, indication for use, typical clinical use, operational characteristics, and fundamental technological characteristics.

Table 5-1. Side-by-Side Comparison of the LFO System with the Predicate Device

Characteristic	**Proposed** **LFO System**	**Primary Predicate** **LFO System K222764**	**Reference Predicate** **Dentsply International IN-OVATION C brackets K060837**
Product Codes / Regulations	NJM (Orthodontic Ceramic Bracket, 21CFR 872.5470)	NJM (Orthodontic Ceramic Bracket, 21CFR 872.5470)	NJM (Orthodontic Ceramic Bracket, 21CFR 872.5470)
Indications for Use	The LFO System is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients	The LFO System is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients	The In-Ovation C is an orthodontic appliance system used to correct malocclusions in orthodontic patients using off-the-shelf orthodontic systems.

Characteristic	Proposed LFO System	Primary Predicate LFO System K222764	Reference Predicate Dentsply International IN-OVATION C brackets K060837
	using patient-matched orthodontic appliances.	using patient-matched orthodontic appliances.	
Sequence of Treatment Plan or Mode of Use	LightForce Orthodontics (LFO) receives the patient's digital data via commercially available communications tools from the DDS/DMD. LFO prepares a final tooth setup and bracket placement plan and returns the digital data back to the DDS/DMD. The orthodontist can then view, measure and modify the case using the TPS. Once approved, brackets and jigs are manufactured and shipped to the DDS/DMD.	LightForce Orthodontics (LFO) receives the patient's digital data via commercially available communications tools from the DDS/DMD. LFO prepares a final tooth setup and bracket placement plan and returns the digital data back to the DDS/DMD. The orthodontist can then view, measure and modify the case using the TPS. Once approved, brackets and jigs are manufactured and shipped to the DDS/DMD.	In-Ovation C brackets are manufactured by Dentsply International and shipped to the DDS/DMD or a reseller.
Bracket Material	Ceramic	Ceramic	Ceramic
Clip material	Nickel Titanium	N/A	Cobalt chromium, known to contain Nickel
Clip Biocompatibility Surface Treatment	Electropolished NiTi or Gold Rhodium Coating	N/A	Gold Rhodium Coating
Manufacturing Method	3D Printed	3D printed	Injection molded
Analysis Methods	N/A	N/A	N/A

Characteristic	Proposed LFO System	Primary Predicate LFO System K222764	Reference Predicate Dentsply International IN-OVATION C brackets K060837
Non-sterile, single use	Yes	Yes	Yes
Bracket Base	Mechanical Lock Base	Mechanical Lock Base	Mechanical Lock Base
Bracket Design	Arch wire slot, tie wings for ligature, and identification marks for placement. Hooks for ligation, for additional tooth movement. A ceramic body with rounded corners and edges. Slot to hold orthodontic wires. Self-ligating metal clip to retain orthodontic wires.	Arch wire slot, tie wings for ligature, and identification marks for placement. Hooks for ligation, for additional tooth movement. A ceramic body with rounded corners and edges. Slot to hold orthodontic wires. Non-self-ligating	Arch wire slot, tie wings for ligature, and identification marks for placement. Hooks for ligation, for additional tooth movement. A ceramic body with rounded corners and edges. Slot to hold orthodontic wires. Self-ligating metal clip to retain orthodontic wires.

Additional reference predicate device with the same chemical composition as the LFO clip material:

- CDB Self Ligating Bracket 8F (K160957) by CDB Corporation. CDB Self Ligating Bracket 8F is a self ligating ceramic bracket with a Nickel titanium clip.

Conclusion:

Based on the information provided in Table 5-1 and the results from the nonclinical performance testing and the biocompatibility assessment the LFO System brackets with the inclusion of optional metal clips are substantially equivalent to the listed predicate device in terms of indications for use and technological characteristics and is safe and effective. Further, any

differences are considered minor and do not raise new issues of safety and effectiveness of the LFO System when compared to the predicate device.