September 14, 2022

LightForce Orthodontics
℅ Prithul Bom
Official Correspondent
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K222764
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 12, 2022
Received: September 13, 2022

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, 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)*
K222764

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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TAB 5

510(K) SUMMARY

510(k) SUMMARY
LightForce Orthodontics' LightForce Orthodontic System

Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared

LightForce Orthodontics
44 Third Ave
Burlington, MA 01803

Phone: 800-481-0185
Email: kelsey@lightforceortho.com

Contact Person: Kelsey Fafara

Date Prepared: August 10, 2022

Name of Device and Name/Address of Sponsor

LightForce Orthodontic System

LightForce Orthodontics
44 Third Ave
Burlington, MA 01803

Trade/Proprietary Name of Device: LightForce Orthodontic System

Common or Usual Name: Orthodontic Ceramic Bracket and Accessory

Classification Name: Orthodontic Ceramic Bracket, 21CFR§872.5470

Regulatory Class: II

Product Code: NJM

Predicate Devices:

Primary Predicate: Signature Orthodontics' Signature Orthodontic System (K181271)

Trade/Proprietary Name of Device: Signature Orthodontic System

Common or Usual Name: Orthodontic Ceramic Bracket and Accessory

Classification Name: Orthodontic Ceramic Bracket, 21CFR§872.5470, Product code: NJM

Device Description

The LightForce Orthodontic System (LFO System) is a treatment planning software (TPS) and orthodontic appliance system used to correct malocclusions in orthodontic patients using patient-matched orthodontic appliances.The orthodontist uses the TPS (K200148) to select and order the patient-specific orthodontic brackets. The TPS allows the orthodontist to diagnose the patient, plan treatment, and position the orthodontic brackets based on a digital impression of the patient - the outcome of the TPS is a prescription for the patient-specific orthodontic brackets. The LFO System consists of patient-specific ceramic brackets, patient-specific bracket placement jigs, arch wire templates, and a TPS for viewing, measuring, and modifying cases. LightForce Orthodontics' (LFO) operators and the orthodontists use the TPS to generate a prescription of their choosing. LFO then manufactures the patient-specific brackets and placement jigs using proprietary additive manufacturing techniques. The orthodontist then bonds the brackets to the teeth using the optional placement jig and ligates wires to enable tooth movement. The LFO System does not contain commercially-available or patient-specific shaped arch wires, ligatures, or adhesives that affixes the brackets to the teeth.

Intended Use / Indications for Use

The indications for use are the same between this submission and the primary predicate K181271.

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.

The LightForce Orthodontic System in the primary predicate (K181271) is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients using patient-matched orthodontic appliances. This current submission provides hardware updates to the hardware delivered in the primary predicate.

Technological Characteristics

LightForce Orthodontic System is similar to other legally marketed devices - while the patient-specific ceramic brackets are equivalent to the Signature Orthdontic Brackets of K181271. Table 6-1 provides a comparison of the LFO System to the predicate devices.

The LFO System patient-specific brackets, like its predicate Signature Orthodontic, are composed of a polycrystalline alumina with a twin bracket design consisting of tie-wings for ligation, a primary arch wire slot and auxiliary slots. There are rounded corners and edges along with a rounded hook on the distal-gingival tie wing of canine brackets to accommodate accessories during orthodontic treatment. These design features allow a ligature wire, in tension, to move the bonded brackets along a designated path until the desired tooth position is

achieved. The brackets are non-self-ligating with a mechanical locking base design and built through additive manufacturing methods.

Non-clinical Performance Testing

Bench testing was performed to ensure that the patient-specific brackets were similar to the LFO System predicate, Signature Orthodontic System. Performance testing consisted of shear bond strength and torque strength. Tensile testing, wire friction testing and bracket strength (fracture) testing were also completed as comparison tests.

1. Shear bond strength is the load per unit area required to remove a bonded bracket from a tooth when a shear force is applied in the occlusal-gingival direction. The shear bond strength of LFO System brackets is equivalent to or better than the predicate device.
2. Torque strength is the torque exerted on the bracket at fracture, when subjected to arch wire torsion. The torque strength of LFO System brackets is equivalent to or better than the predicate device.
3. Friction (wire drag) force is the force required to drag a ligated stainless-steel wire through the primary slot of the bracket. The friction (wire drag) force of the LFO System brackets is equivalent to the predicate device.
4. Tensile bond strength is the load per unit area required to remove a bonded bracket from a tooth when a tensile force is applied to a stainless-steel wire ligated to the primary slot of the bracket. The tensile bond strength of LFO System brackets is equivalent to the predicate device.
5. Tie-wing tensile fracture strength is the fracture strength of the tie-wing complex when a tensile load is placed directly under the tie wing. The tie wing tensile fracture strength of LFO System brackets is equivalent to the predicate device.

Clinical Performance Testing

No clinical performance testing was conducted on LFO System brackets.

Device Comparison Tables

The following table, Table 5-2, provide a comparison of the device features, functions, and performance characteristics between the LightForce Orthodontic System (LFO System) and its predicate devices.

Table 5-2: Comparison of LFO System and Predicate Devices			
ITEM	**PRIMARY PREDICATE Signature Orthodontic System K181271**	**LightForce Orthodontic System**	**Similarities or differences**

Description	The Signature Orthodontic System (SO System) is a treatment planning software (TPS) and orthodontic appliance system used to correct malocclusions in orthodontic patients using patient-matched orthodontic appliances. The SO System consists of patient-specific ceramic brackets, patient-specific bracket placement jigs, arch wire templates, and a TPS for viewing, measuring, and modifying cases. Signature Orthodontics' (SO) operators and the orthodontists use the TPS to generate a prescription of their choosing. SO then manufactures the patient-specific brackets and placement jigs using proprietary additive manufacturing techniques. The orthodontist then bonds the brackets to the teeth using the optional placement jig and ligates wires to enable tooth movement. The SO System does not contain commercially-available or patient-specific shaped arch wires, ligatures, or adhesives that affixes the brackets to the teeth.	The LightForce Orthodontic System (LFO System) is a treatment planning software (TPS) 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 bracket placement jigs, arch wire templates, and a TPS for viewing, measuring, and modifying cases. LightForce Orthodontics' (LFO) operators and the orthodontists use the TPS to generate a prescription of their choosing. LFO then manufactures the patient-specific brackets and placement jigs using proprietary additive manufacturing techniques. The orthodontist then bonds the brackets to the teeth using the optional placement jig and ligates wires to enable tooth movement. The LFO System does not contain commercially-available or patient-specific shaped arch wires, ligatures, or adhesives that affixes the brackets to the teeth.	**Identical**
Product Codes / Regulations	NJM (Orthodontic Ceramic Bracket, 21CFR§872.5470)	NJM (Orthodontic Ceramic Bracket, 21CFR§872.5470)	**Identical**
Indications for Use	The Signature Orthodontic System is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients using	The LightForce Orthodontic System is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients using	**Identical**

	patient-matched orthodontic appliances.	patient-matched orthodontic appliances.	
Sequence of Treatment Plan or Mode of Use	Signature Orthodontics (SO) receives the patient's digital data via commercially available communications tools from the DDS/DMD. SO 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.	**Identical**
Bracket Material	Polycrystalline Alumina Ceramic	Ceramic	**Identical**
Manufacturing Method	3D printed	3D Printed	**Identical**
Analysis Methods	N/A	N/A	**Identical**
Non-sterile, single use	Yes	Yes	**Identical**
Bracket Base	Mechanical Lock Base	Mechanical Lock Base	**Identical**
Bracket Design	Arch wire slot, tie wings for ligature, and identification marks for placement. Hooks for ligation, for additional tooth movement. Printed 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. Printed ceramic body with rounded corners and edges. Slot to hold orthodontic wires. Non-self-ligating	**Identical**

Substantial Equivalence

The LightForce Orthodontic System (LFO System) is the same as the predicate device; Signature Orthodontic Brackets. The LFO System has the same intended uses/indication for uses, technological characteristics, and principles of operation as its predicate devices. The performance data provided above demonstrates that the LFO System performs at an equivalent

or better level compared to Signature Orthodontic Brackets. The minor technological differences between the LFO System and the predicate device, Signature Orthodontic brackets, raise no new issues. There are no alterations in the intended use or the underlying technology or science involved. Thus, the LightForce Orthodontic System is the same as its predicates.

Conclusion

Additionally, the LFO System has the same intended use, composition, design, function, physical properties and performance as its predicate devices. As shown in our performance data, the difference in manufacturing method does not impact the device's intended use and performance. The results from the nonclinical performance testing and the biocompatibility assessment demonstrate that LFO System brackets, along with the appropriate arch wires, constitute standard orthodontic appliances which are equivalent to existing appliances used in the clinical environment.