February 21, 2020

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

Re: K200148
Trade/Device Name: LightForce Orthodontic System (LFO System)
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: PNN, NJM
Dated: January 21, 2020
Received: January 22, 2020

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200148

Device Name

LightForce Orthodontic System

Indications for Use *(Describe)*

The LightForce Orthodontic System is a treatment planning software (TPS) 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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TAB 6 - 510(k) Summary

K200148 - 510(k) SUMMARY

LightForce Orthodontics' LightForce Orthodontic System

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

LightForce Orthodontics
1035 Cambridge Street
Cambridge, MA 02141

Phone: 800-481-0185
Facsimile: N/A
Email: amos@lightforceortho.com

Contact Person: Amos N Benninga

Date Prepared: February 20, 2020

Name of Device and Name/Address of Sponsor

LightForce Orthodontic System
LightForce Orthodontics
1035 Cambridge Street
Cambridge, MA 02141

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

Primary Predicate: LightForce Orthodontics' LightForce Orthodontic System (K183542)
Reference Device: LightForce Orthodontics' LightForce Orthodontic System (K181271)

(Note: Previously known as Signature Orthodontic System)

Device Description and Justification

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,modifying cases and submitting orders. 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.

The change is to upgrade LFO System's Treatment Planning Software (TPS) from version 3.1 to version 4.0. TPS version 3.1 was originally cleared in K183542 and the LFO System was originally cleared in K181271. TPS version 4.0 provides improved software architecture, updated hosting infrastructure and improvements to the user interface to better match the intended use of the product based on customer feedback and validation input.

A comparison of TPS 3.1 and TPS 4.0 shows that both software provide the same features and functional workflows is evidence of substantial equivalence. The replacement software is identical in performance and function to the previously used software.

Indications for Use

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.

Comparison to Primary Predicate and Reference Device

The LightForce Orthodontic System in the primary predicate (K183542) 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 software updates to the software delivered in the primary predicate.

The LightForce Orthodontic System in the reference predicate (K181271) is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients using patient-matched orthodontic appliances.

Note: this current submission (the subject device) is leveraging performance testing such as shear bond strength, torque strength, tensile strength, wire drag force, etc. of the brackets in the reference device, which remain identical in the subject's predicate device, and the subject device. The current submission only differs from the reference device in the software component (Treatment Planning Software / TPS) which has changed. The changes are described and documented in this submission.

Non-clinical Performance Testing

Validation testing of the TPS was performed in accordance with LFO's design control activities for software and to the software's Test Plan. Validation results, Table 6-1, show that the version of the TPS tested performed equivalent to the software component of the primary predicate (K183542).

Table 6-1 - LFO System TPS Performance Testing

LFO System (K181271)	**LFO System TPS 3.1 (K183542)**	**LFO System TPS 4.0 (current submission)**	**Equivalence Result**
4.1 Diagnosis - viewing of patient's digital impression	4.1 Diagnosis - viewing of patient's digital impression	4.1 Diagnosis - viewing of patient's digital impression	Equivalent (Test Report)
4.1 Diagnosis - successful diagnosis of patient's malocclusion	4.1 Diagnosis - successful diagnosis of patient's malocclusion	4.1 Diagnosis - successful diagnosis of patient's malocclusion	Equivalent (Test Report)
4.2 Planning - successful movement of patient's teeth (within the software)	4.2 Planning - successful movement of patient's teeth (within the software)	4.2 Planning - successful movement of patient's teeth (within the software)	Equivalent (Test Report)
4.3 Planning - successful movement of brackets	4.3 Planning - successful movement of brackets	4.3 Planning - successful movement of brackets	Equivalent (Test Report)
4.4 Data Handling - case delivered securely and uncorrupted	4.4 Data Handling - case delivered securely and uncorrupted	4.4 Data Handling - case delivered securely and uncorrupted	Equivalent (Test Report)

Clinical Performance Testing

No clinical performance testing was conducted on LFO System brackets.

Device Comparison Tables

The following tables, Table 6-2 and 6-3, provide a comparison of the device features, functions, and performance characteristics between the LightForce Orthodontic System (LFO System) and its predicate devices.

Table 6-2 - LFO System TPS Feature Comparison

Workflow Function	**LFO System (K181271)**	**LFO System v3.1 (K183542)**	**LFO System v4.0 (current submission)**	Similarities	Differences
Indications for Use	The LightForce Orthodontic System (K183542) 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 (K183542) 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 is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients using patient-matched orthodontic appliances.	Identical	
4.1 Diagnosis - viewing patient's digital impression	Rendering of impression using 3D files	Rendering of impression using 3D files	Rendering of impression using 3D files	Identical	
4.1 Diagnosis - viewing patient's digital	Rotate impression display	Rotate impression display	Rotate impression display	Identical	

impression					
4.1 Diagnosis - viewing patient's digital impression	Zoom impression display	Zoom impression display	Zoom impression display	Identical	
4.1 Diagnosis - viewing patient's digital impression	Pan impression display	Pan impression display	Pan impression display	Identical	
4.1 Diagnosis - successful diagnosis of patient's malocclusion	Hide/Show individual arches	Hide/Show individual arches	Hide/Show individual arches	Identical	
4.2 Planning - move teeth based on desired final location	Rotate & translate around tooth X,Y,Z	Rotate & translate around tooth X,Y,Z	Rotate & translate around tooth X,Y,Z as well as Jaw and TMJ axis		Improved movement accuracy by moving around desired axis.
4.3 Planning - move brackets based on desired final location	Move brackets controls	Move brackets controls	Move brackets controls	Identical	
4.4 Data Handling - case data delivered securely and uncorrupted	Impression data transmitted over HTTPS	Impression data transmitted over HTTPS	Impression data transmitted over HTTPS	Identical	

Table 6-3 - Device Comparison				
Item	**Reference Predicate K181271 LightForce Orthodontic System;**	**Primary Predicate K183542 LightForce Orthodontic System; TPS 3.1**	**LightForce Orthodontic System; TPS 4.0**	**Comments**
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 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. LightForce 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	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 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. LightForce 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	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 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. LightForce 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	Identical

	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.	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.	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.	
Product Codes / Regulations	NJM (Orthodontic Ceramic Bracket, 21CFR§872.5470)	NJM (Orthodontic Ceramic Bracket, 21CFR§872.5470)	NJM (Orthodontic Ceramic Bracket, 21CFR§872.5470)	Identical
Indications for Use	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 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 is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients using patient-matched orthodontic appliances.	Identical
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.	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

Manufacturing Method	Final desired arrangement of teeth, brackets, wires and jigs are designed with the guidance of LFO internal computer software using a 3-D model of the patient. The Treatment Planning Software allows the clinician to review, measure, and modify the case. Internal LFO software generates the 3D image file that proprietary additive manufacturing equipment uses to create the brackets and indirect bonding (IDB) tray.	Final desired arrangement of teeth, brackets, wires and jigs are designed with the guidance of LFO internal computer software using a 3-D model of the patient. The Treatment Planning Software allows the clinician to review, measure, and modify the case. Internal LFO software generates the 3D image file that proprietary additive manufacturing equipment uses to create the brackets and indirect bonding (IDB) tray.	Final desired arrangement of teeth, brackets, wires and jigs are designed with the guidance of LFO internal computer software using a 3-D model of the patient. The Treatment Planning Software allows the clinician to review, measure, and modify the case. Internal LFO software generates the 3D image file that proprietary additive manufacturing equipment uses to create the brackets and indirect bonding (IDB) tray.	Identical

Conclusion

The LightForce Orthodontics' LightForce Orthodontics System presented in this 510(k) submission and its primary predicate the LightForce Orthodontic System (K183542) and its reference predicate the LightForce Orthodontics System (K181271) are substantially equivalent in intended use and technological characteristics.