Signature Orthodontics
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, Nw
Buffalo, Minnesota 55313

January 2, 2019

Re: K183542
Trade/Device Name: Signature Orthodontic System
Regulation Number: 21 CFR Orthodontic Plastic Bracket
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NJM
Dated: December 17, 2018
Received: December 20, 2018

Dear Mark Job:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2019.01.02 11:18:54 -05'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*

Device Name
Signature Orthodontic System

Indications for Use *(Describe)*
The Signature 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

TAB 6

510K SUMMARY

510(k) SUMMARY

Signature Orthodontics' Signature Orthodontic System

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

Signature Orthodontics
1035 Cambridge Street
Cambridge, MA 02141

Phone: 540-229-1236
Facsimile: N/A
Email: alfred@soiboston.com

Contact Person: Alfred Charles Griffin III

Date Prepared: November 13, 2018

Name of Device and Name/Address of Sponsor

Signature Orthodontic System

Signature Orthodontics
1035 Cambridge Street
Cambridge, MA 02141

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

Regulatory Class: II

Product Code: NJM

Predicate Devices:

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

Device Description and Justification

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 change is to replace Meshmixer 3.4 as the software component of the SO System with Treatment Planning 3.1 The software component of the SO System was originally cleared in K181271. Meshmixer is Off-the-Shelf (OTS) Software, the new software has been developed by SO exclusively. The functional requirements of the software component are unchanged. A comparison of Treatment Planning 3.1 and Meshmixer 3.4 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.

Intended Use / Indications for Use

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

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

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

Non-clinical Performance Testing

Validation testing of the TPS was performed in accordance with SO'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 (K181271).

Table 6-1 – SO System TPS Performance Testing Summary

Primary PREDICATE K181271 Signature Orthodontic System; TPS Off-the-shelf	Signature Orthodontic System; TPS 3.1	Equivalence Result
4.1 Diagnosis - viewing patient's digital impression	4.1 Diagnosis - viewing 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	Equivalent (Test Report)

4.4 Data Handling - case data delivered securely and un-corrupted	4.4 Data Handling - case data delivered securely and un-corrupted	Equivalent (Test Report)
4.1 Diagnosis - viewing and measuring patient's digital impression	4.1 Diagnosis - viewing and measuring patient's digital impression	Equivalent (Test Report)

Clinical Performance Testing

No clinical performance testing was conducted on SO System brackets.

Device Comparison Tables

The following tables, Tables 6-2 and 6-3, provide a comparison of the device features, functions, and performance characteristics between the Signature Orthodontic System and its predicate devices.

Table 6-2 – SO System TPS Feature Comparison

Workflow Function	SO System TPS – Off-the-shelf	SO System TPS – TPS 3.1	Similarities	Differences
4.1 Diagnosis - viewing patient's digital impression	Rendering of impression using triangle meshes read from STL files	Rendering of impression using triangle meshes read from STL files	Identical	
4.1 Diagnosis - successful diagnosis of patient's malocclusion	Hide/show individual arches	Hide/show individual arches	Identical	TPS 3.1 enables hide/show arches with a single click. OTS requires multiple clicks.
4.4 Data Handling - case data delivered securely and un-corrupted	Secure link used to download STL files, then File -> Open in device.	Open secure link in web browser.	Secure link communicated using the orthodontist's confirmed e-mail addresses Impression data transmitted over HTTPs	TPS 3.1 removes the download STL files step and integrates the transfer with the loading of the software by the user's web browser.
4.1 Diagnosis - viewing and measuring patient's digital impression	Rotate impression display	Rotate impression display	Identical	
	Pan impression display	Pan impression display	Identical	
	Zoom impression display	Zoom impression display	Identical	

	Point-to-point measurement	N/A		The requirements specification for TPS 3.1 does not include point-to-point measurement.

Table 6-3 – Device Comparison			
ITEM	**Primary PREDICATE K181271 Signature Orthodontic System; TPS Off-the-shelf**	**Signature Orthodontic System; TPS 3.1**	**Comments**
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 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.	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 patient-matched orthodontic appliances.	The Signature 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	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.	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.	Identical
Manufacturing Method	Final desired arrangement of teeth, brackets, wires and jigs are designed with the guidance of SO 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 SO 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 SO 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 SO software generates the 3D image file that proprietary additive manufacturing equipment uses to create the brackets and indirect bonding (IDB) tray.	Identical

Conclusion

The Signature Orthodontics' Signature Orthodontic System presented in this 510(k) submission and its predicate the Signature Orthodontic System (K181271) are substantially equivalent in materials, performance and safety characteristics.