



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

June 13, 2018

Re: K181271  
Trade/Device Name: Signature Orthodontic System  
Regulation Number: 21 CFR 872.5470  
Regulation Name: Orthodontic plastic bracket  
Regulatory Class: Class II  
Product Code: NJM  
Dated: May 11, 2018  
Received: May 14, 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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
Mary S. Runner -S

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

## Indications for Use

510(k) Number (if known)

K181271

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.

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## TAB 6

### 510K SUMMARY

#### 510(k) SUMMARY

#### Signature Orthodontics' Signature Orthodontic System (K181271)

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

Signature Orthodontics 16  
Miner Street, Suite 406  
Boston, MA 02215

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

Contact Person: Alfred Charles Griffin III

Date Prepared: June 13, 2018

#### Name of Device and Name/Address of Sponsor

Signature Orthodontic System

Signature Orthodontics  
16 Miner Street, Suite 406  
Boston, MA 02215

**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:** TOMY Orthodontic Ceramic Brackets 1.1 (K160615)

**Reference Predicate:** Insignia Digicast (K123118)

## **Device 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.

## **Intended Use / 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 differences in the SO System indication for use from its predicates does not affect the equivalence of the devices when used as labeled. The treatment planning software refers to the computer aided system which aids orthodontic diagnostics and treatment within the Insignia Digicast indication. The patient-matched orthodontic appliances and correction of malocclusions relate to the ceramic brackets and orthodontic movement discussed in the TOMY indication. The patient-matched brackets do not raise any levels of concern or efficacy as shown through the substantially equivalent performance tests completed between the SO System brackets and the TOMY brackets.

## **Technological Characteristics**

Signature Orthodontic System is substantially equivalent to two other legally marketed devices. The TPS has similar functionally and intended for the same use as Insignia Digicast (K123118) while the patient-specific ceramic brackets are equivalent to the TOMY Orthodontic Ceramic Brackets 1.1 (K160615). Table 6-1 provides a comparison of the SO System to the predicate devices.

The SO System patient-specific brackets, like its predicate TOMY Orthodontic Ceramic Brackets 1.1, 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 substantially equivalent to the SO System predicate, TOMY Orthodontic Ceramic Brackets 1.1. 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 SO System brackets is equivalent to or better than the predicate device because the average value of the SO System brackets' shear bond strength was statistically significantly higher than that of 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 SO System brackets is equivalent to the predicate device because there were no statistically significant differences between the two groups. The average value of the SO System brackets' torque strength was slightly higher than that of 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 SO System brackets is equivalent to the predicate device because there were no statistically significant differences between the two groups. The average value of the SO System brackets' friction (wire drag) force was slightly lower than that of 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 SO System brackets is equivalent to or better than the predicate device because the average value of the SO System brackets' tensile bond strength was statistically significantly higher than that of 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 SO System brackets is equivalent to the predicate device because there were no statistically significant differences between the two groups. The average value of the SO System brackets' tie wing fracture strength was slightly lower than that of the predicate device.

Due to the different methods of manufacturing from its predicate, the SO System brackets were evaluated for ISO 27020: "Dentistry - Brackets and Tubes for Use in Orthodontics" compliance and biocompatibility using standard risk assessment techniques and guidelines according to ISO 10993-1, "Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process". Biocompatibility testing performed included genotoxicity, cytotoxicity (agarose and elution methods), sensitization, oral toxicity, irritation, and chemical characterization.

### **Clinical Performance Testing**

No clinical performance testing was conducted on SO System brackets.

**Table 6-1: Comparison of SO System and Predicates**

<b>ITEM</b>	<b>Primary PREDICATE K160615 TOMY Orthodontic Ceramic Brackets 1.1</b>	<b>Reference PREDICATE K123118 Digital Study Model (Insignia Digicast)</b>	<b>Signature Orthodontic System</b>
<b>Description</b>	Orthodontic Ceramic Brackets 1.1 are designed to move teeth to improve their alignment. Orthodontic Ceramic Brackets 1.1 are bonded to natural teeth by dental professionals to connect with orthodontic wires to cause tooth movement to a more preferred position.	Insignia Digicast is a software product and service that creates digital models of patients' teeth, which are used primarily to record the status of a patients' dentition prior to treatment. Clinicians may also use the digital model to support their diagnosis. The Insignia Digicast system scans a traditional impression, processes the scan, and electronically delivers a digital study model to the dental professional. The dental professional may view, measure, and analyze the study model using the Insignia Digicast three-dimensional viewer software. The main analysis tools include TJ Moyers, Bolton analyses, ABO scoring, and Arch and Overbite/Overjet measurements. There are no accessories or patient contacting components of Insignia Digicast.	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.
<b>Product Codes/Regulations</b>	NJM (Orthodontic Ceramic Bracket, 21CFR§872.5470)	DYW (Orthodontic Plastic Bracket, 21CFR§872.5470) EJF (Orthodontic Metal Bracket, 21CFR§872.5410)	NJM (Orthodontic Ceramic Bracket, 21CFR§872.5470)

		NJM (Orthodontic Ceramic Bracket, 21CFR§872.5470)	
<b>Indications for Use</b>	Orthodontic Ceramic Brackets 1.1 are indicated for orthodontic movement of natural teeth.	Insignia Digicast is a computer aided system intended for use as an aid in orthodontic diagnostics for use by dental professionals trained in orthodontic treatment including radiographic analyses and diagnostics.	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.
<b>Sequence of Treatment Plan or Mode of Use</b>	The Orthodontic Ceramic Brackets 1.1 are bonded to natural teeth by dental professionals to connect with orthodontic wires to cause tooth movement to a more preferred position.	Scans a traditional impression, processes the scan, and electronically delivers a digital study model to the dental professional	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.
<b>Bracket Material</b>	Polycrystalline Alumina Ceramic	N/A	Polycrystalline Alumina Ceramic
<b>Manufacturing Method</b>	Ceramic Injection Molded	A orthodontal professional takes an impression of the patient's teeth by alginate or PVS. The impression is scanned and converted to a digital model. This model is then uploaded for use by the practitioner.	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.
<b>Analysis Methods</b>	N/A	Bolton analysis, Tanaka-Johnson Moyers Analysis, Space Analysis, and ABO Discrepancy Index Scoring	N/A
<b>Non-sterile, single use</b>	Yes	N/A	Yes
<b>Bracket Base</b>	Mechanical Lock Base	N/A	Mechanical Lock Base
<b>Bracket Design</b>	Arch wire slot, tie wings for ligation, and identification marks for placement. Hooks for ligation, for additional tooth movement. Molded ceramic body with rounded corners and edges. Slot to hold orthodontic wires. Non-self-ligating and self-ligating	N/A	Arch wire slot, tie wings for ligation, 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

### **Substantial Equivalence**

The Signature Orthodontic System (SO System) is substantially equivalent to the predicate devices; Insignia Digicast, and TOMY Orthodontic Ceramic Brackets 1.1. The SO 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 SO System performs at an equivalent or better level compared to Insignia Digicast, and TOMY Orthodontic Ceramic Brackets 1.1. The minor technological differences between the SO System and the predicate devices, Insignia Digicast, and TOMY Orthodontic Ceramic Brackets 1.1, raise no new issues. There are no alterations in the intended use or the underlying technology or science involved. Thus, the Signature Orthodontic System is substantially equivalent to its predicates.

### **Conclusion**

The difference between the SO System and its predicates is the manufacturing method. Additionally, the SO 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 SO System brackets, along with the appropriate arch wires, constitute standard orthodontic appliances which are equivalent to existing appliances used in the clinical environment.