February 19, 2021

Swift Health Systems, Inc.
Alicia Mszyca
Director, Regulatory Affairs
111 Academy, Suite 150
Irvine, California 92617

Re: K203442
Trade/Device Name: Inbrace Orthodontic System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN, EJF, DZC
Dated: November 19, 2020
Received: November 23, 2020

Dear Alicia Mszyca:

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 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)*
K203442

Device Name
Inbrace Orthodontic System

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

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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SWIFT
Health Systems, Inc.

K203442 - 510(k) SUMMARY

I. SUBMITTER

Swift Health Systems, Inc. (dba Inbrace)
111 Academy, Suite 150
Irvine, California 92617
Contact Person: Alicia Mszyca
Telephone Number: (949) 774-2239

Date Prepared: November 19, 2020

II. DEVICE

Trade Name:	**Inbrace Orthodontic System**
Common Name:	Orthodontic Software and Appliance
Device Class:	II
Classification Name:	Orthodontic Plastic Bracket, 21 CFR § 872.5470
Product Codes:	PNN (Orthodontic Software), EJF (Orthodontic Metal Bracket) & DZC (Orthodontic Wire)

III. PRIMARY PREDICATE

Insignia (Ormco Corporation), K121524

IV. DESCRIPTION OF THE DEVICE SUBJECT TO PREMERKET NOTIFICATION

The Inbrace Orthodontic System is a treatment planning software and orthodontic appliance system designed to be affixed to the lingual side of the teeth to correct malocclusions in orthodontic patients.

The Inbrace software creates a 3-dimentional (3D) model of the patient's dentition based on the digital scans of the patient's dentition provided by the orthodontist. The Inbrace technicians use this computer model to determine the placement of the brackets to achieve the intended repositioning of the teeth (ideal occlusion). The model is reviewed and approved by the orthodontist prior to fabrication of the actual orthodontic appliances comprising of metal brackets, patient-specific programmed multiloop arch wires, and patient-specific bracket placement trays (indirect bonding trays) used to affix the brackets in position on the patient's teeth. The brackets are assembled into the indirect bonding trays and bonded with a commercially available dental adhesive.

V. INDICATIONS FOR USE

Inbrace Orthodontic System is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients using appliances individualized for the orthodontic patient.

VI. COMPARISON TO PREDICATE DEVICE

The Inbrace Orthodontic System is substantially equivalent to Insignia (K121524). The Inbrace Orthodontic System consists of the same components (proprietary treatment planning software and orthodontic appliances consisting of patient-specific shaped archwires, metal brackets and patient-specific indirect bonding trays to affix brackets into position), has the same technological characteristics, principles of operation, treatment sequence, mode of use, manufacturing methodology and is intended for the same use as Insignia.

The comparison table below demonstrates system similarities used for the determination of substantial equivalence between the subject and predicate device.

Features	Inbrace Orthodontic System- subject device	Insignia – K121524	Comparison
Intended use	Inbrace Orthodontic System is a computer-guided system intended for use as an aid in orthodontic treatment planning for use by dental orthodontic professionals trained in orthodontic treatment including radiographic analyses and treatment planning. Inbrace contains patient-specific individually designed arch wires and wire-specific brackets that apply continuous gentle force to reposition the teeth. It also uses patient-specific indirect bonding trays to affix the brackets in position.	Insignia is a computer - guided system intended for use as an aid in orthodontic treatment planning for use by dental orthodontic professionals trained in orthodontic treatment including radiographic analyses and treatment planning. Insignia is intended for use with commercially available and /or individually modified brackets and wires that apply continuous gentle force to reposition the teeth. It uses patient specific foam placement jigs to affix the brackets in position.	Intended for same purpose – movement of teeth, thus substantially equivalent

Indication for use statement	Inbrace Orthodontic System is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients using appliances individualized for the orthodontic patient.	Insignia Orthodontic System is a treatment planning software and orthodontic appliance system used to correct malocclusions in orthodontic patients using appliances individualized for the orthodontic patient.	Same
Principles of operation	• A 3D digital scan of patient's dentition is provided by the orthodontist • A 3D end-of-treatment outcome model is generated • The 3D model is sent to the orthodontist for review and approval • Bracket placement trays (indirect bonding (IDB) trays) are manufactured to position the brackets on the patient's teeth as prescribed by the orthodontist • Patient-specific archwires are fabricated based on the 3D model • Brackets are adhered to the patient's teeth with a commercially available adhesive	• A 3D digital model is created on a stone model or a patient's dental impression • A 3D end-of-treatment outcome model is generated • The 3D model is sent to the orthodontist for review • Bracket placement jigs are manufactured to position the brackets on the patient's teeth as prescribed by the orthodontist • Patient-specific arch wires are provided • Brackets are adhered to the patient's teeth with a commercially available adhesive	Same. Both consist of 1) treatment using a 3D digital scan, 2) 3D model is sent to orthodontist for review and approval, 3) bracket placement using either an IDB tray (Inbrace) or placement jigs (Insignia). The difference in placement does not affect performance thus, substantially equivalent.

Mode of Use	Inbrace brackets are fabricated and fixed to the patient's teeth using patient-specific indirect bonding trays. Patient-specific archwires of traditional metallurgy are fabricated and provided. The appliances are fixed to the teeth with the commercially available adhesives.	Either patient-specific (individually modified) or standard appliances are fixed to the patient's teeth using patient specific foam placement trays. Patient specific archwires of traditional metallurgy are provided. The appliances are fixed to the teeth with commercially available adhesives.	Same
Bracket material	Stainless steel /nickel-titanium	Stainless steel /ceramic/ plastic	Same for metal brackets. Inbrace system does not use plastic or ceramic brackets.
Arch wire material	Nickel-titanium/ copper-nickel-titanium	Stainless steel/nickel-titanium/ Beta titanium	Substantially equivalent
Positioning device material	Clear 3D printing resin	Plastic foam	No impact on performance thus substantially equivalent.
Description of appliance placement	Affixed and removed by clinician	Affixed and removed by clinician	Same
Manufacturing method	Final desired arrangement of brackets, wires and indirect bonding trays are designed with the guidance of Inbrace software based on 3D scans of the patient's dentition. The software allows the clinician to review, alter and approve	Final desired arrangement of brackets, wires and jigs are designed with the guidance of computer software using 3dimentional models of the patient. In office software allows the clinician to review, alter and approve desired result	Same

	desired result and appliances. Software generates codes/image file that drives machinery to manufacture the appliances.	and appliances. Software generates code that drives machinery to manufacture the appliances.	

VII. PERFORMANCE DATA

The following information was provided to support the submission:

Biocompatibility Testing

The biocompatibility evaluation of the Inbrace appliances was conducted in accordance with ISO 10993-1 Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing within a Risk Management Process as recognized by FDA.

The results demonstrate the patient-contacting components including brackets, archwires, and indirect bonding trays are biocompatible, thus safe for their intended use.

Software Verification and Validation

Inbrace software has been designed, integrated, verified, and validated to confirm its suitability and performance in accordance with the ISO/IEC 62304 standard - Medical device software – software life cycle processes.
The appropriate software documentation consistent with the Level of Concern as described in the FDA guidance titled "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices" was included in this submission.

Clinical Testing

No clinical testing was conducted for this device to support substantial equivalence.

VIII. CONCLUSION

Inbrace Orthodontic System is substantially equivalent to its predicate device Insignia (K121524) in terms of intended use, indication for use, technical and material characteristics as well as operating principles.
Biocompatibility data and software verification and validation demonstrate that the Inbrace Orthodontic System is safe for its intended use.