Specialty Appliance Works, Inc.
% Mark Job
Official Correspondent
Regulatory Technology Services, LLC
1394 25th Street, Nw
Buffalo, Minnesota 55313

January 3, 2019

Re: K183643
Trade/Device Name: Clear Image Aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: December 21, 2018
Received: December 26, 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: 2019.01.03 09:06:24 -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

Specialty Appliances

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
Clear Image Aligners

Indications for Use *(Describe)*
The Clear Image Aligners are indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.

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.

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"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."

510(k) Summary

Date Prepared:	November 16, 2018
Submitter:	Specialty Appliance Works, Inc. 4905 Hammond Industrial Drive Cumming, GA 30041
Contact:	Carolyn Thomas Quality Manager Specialty Appliance Works, Inc. (678) 513-4408 Carolyn.Thomas@specialtyappliances.com
Proprietary Name:	Clear Image Aligners
Common Name:	Sequential Aligners
Classification:	21 CFR 872.5470: Orthodontic plastic bracket; Class II
Product Code:	NXC
Predicate Device:	K173785, Derby Dental Laboratory Custom Clear Aligner System

Intended Use / Indications:

The Clear Image Aligners are indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.

Device Description:

The Clear Image Aligners are a sequential set of removable aligners prescribed by an orthodontist or dentist, used to gradually move a patient's teeth in order to treat misalignment and malocclusion. Each aligner in the sequential set is created by a trained technician utilizing 3Shape orthodontic software (K171634/K152086) and tooth movement recommendations from the prescribing orthodontist/dentist. Aligners are then fabricated from plastic. Corrective force to progressively reposition the teeth is delivered via minor changes from one aligner to the next within the series.

Each aligner set is patient specific and can only be used for an individual patient for whom it is prescribed. Clear Image Aligners are provided non-sterile and are completely removable by the patient and treatment/use may be discontinued at any time.

Non-Clinical Testing:

Specialty Appliance Works, Inc. has completed biocompatibility testing per ISO 10993-1 and its applicable parts, as appropriate for the aligner contact and duration. The mechanical properties of the Essix Ace plastic (K062828) has been previously demonstrated by the manufacturer as appropriate for use with aligners, therefore no additional testing was required.

Clinical Testing:

The performance of sequential aligners in the clinical environment has been well established since the first aligners were cleared by the FDA under product code NXC in 1998. Therefore, clinical testing was not necessary to demonstrate substantial equivalence of the Clear Image Aligners to the predicate device.

Predicate Device Comparison:

Property or Characteristic	Proposed Device Specialty Appliance Works, Inc. Clear Image Aligners	Predicate Device Derby Dental Laboratory Custom Clear Aligner System (K173785)	Comments
Device Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Same as K173785
Product Code	NXC	NXC	Same as K173785
Classification	II	II	Same as K173785
Indications for Use	The Clear Image Aligners are indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.	The Custom Clear Aligner System is indicated for use in the alignment of permanent teeth through orthodontic treatment of misalignment and malocclusion.	Same as K173785
Mode of Action	Alignment of teeth by application of continuous	Alignment of teeth by application of continuous	Same as K173785

Property or Characteristic	Proposed Device Specialty Appliance Works, Inc. Clear Image Aligners	Predicate Device Derby Dental Laboratory Custom Clear Aligner System (K173785)	Comments
	gentle force, by sequential use of preformed plastic trays.	gentle force, by sequential use of preformed plastic trays.	
Method of Use	Each preformed plastic tray is worn by the patient as prescribed by the orthodontist/dentist prior to using the next sequential aligner tray.	Each preformed plastic tray is worn by the patient as prescribed by the dental practitioner, usually a few weeks prior to using the next sequential aligner tray.	Same as K173785
Material	Essix Ace plastic (K062828)	Thin thermoformed polyurethane	Similar to K173785
Prescription or OTC	Prescription	Prescription	Same as K173785
Software Used during manufacturing	Use of 3Shape Ortho System (K171634/K152086)	Use of 3Shape Ortho System (K152086)	Same as K173785
Provided Non-Sterile	Yes	Yes	Same as K173785

Summary of Substantial Equivalence:

Based on the information presented in this submission, Specialty Appliance Works, Inc. concludes that the Clear Image Aligners are substantially equivalent to the predicate device in regard to indications for use, design and technology.