August 23, 2019

OSW Manufacturing, LLC
℅ Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K191990
Trade/Device Name: OSW Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: July 24, 2019
Received: July 25, 2019

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/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,

Srinivas Nandkumar, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191990

Device Name
OSW Aligner System

Indications for Use *(Describe)*
OSW Aligner System is indicated for the alignment of teeth during orthodontic treatment of 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.

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510(k) Summary (K191990)

510(k) Owner	OSW Manufacturing, LLC 35778 Elk Lane, Murrieta, CA 92563 Phone: 408.621.1152
Contact person	Ian Kitching OSW Manufacturing, LLC 35778 Elk Lane, Murrieta, CA 92563 Phone: 408.621.1152 ian@oswaligner.com
Date Prepared	August 23, 2019
Product Code:	
Common Name	Orthodontic Plastic Brackets
Trade Name	OSW Aligner System
Classification Name	aligner, sequential
Regulation	872.5470
Class	Class II
Panel	Dental
Product Code	NXC
Primary Predicate	K171674 Angel Align System

Description

The OSW Aligner System consists of a series of doctor-prescribed, thin, clear plastic removable orthodontic appliances (aligners) and proprietary 3D software. The aligners progressively move the patient's teeth in small increments from their original state to a final treated state.

The OSW Aligner System is intended as an alternative to conventional wire/bracket technology and fixed appliances for the treatment of patients with malocclusion.

The 3D software generates the model of a provisional treated state and then creates a series of models that represent intermediate teeth states. The dental practitioner reviews these models to view, edit or approve the orthodontic treatment plan. The dental practitioner has the option to

reject or request modifications to the setup prior to approving it for aligner fabrication. Once the doctor approves the setup, the series of custom-made aligners are manufactured, packaged, and shipped to the dental practitioner to be dispensed to the patient for treatment.

Indications for Use

OSW Aligner System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.

Technological Characteristics

The predicate and the OSW Aligner System were compared in the following areas and found to have similar technological characteristics and to be equivalent:

Device Comparison Table

	OSW Aligner System	K171674
Indications for Use Statement	The OSW Aligner System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.	The Angel Align System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.
3-D Software Description	The OSW Manufacturing 3-D Software uses a scan of a PVS impression or a digital scan (which represents an untreated state) to generate the image of a final, provisional treated state and then interprets a series of images that represent intermediate teeth states. The dental practitioner then reviews these images and has the option to reject or request modifications to the set-up prior to approving it for aligner fabrication. Once the dental practitioner approves the treatment plan, the software converts the files to produce the series of custom-made aligners	The Angel 3-D Software uses a scan of a PVS impression or a digital scan (which represents an untreated state) to generate the image of a final, treated state and then interprets a series of images that represent intermediate teeth states. The dental practitioner then reviews these images and has the option to reject or request modifications to the set-up prior to approving it for aligner fabrication. Once the dental practitioner approves the treatment plan, the software converts the files to produce the series of custom-made aligners
Mode of Operation for 3-D Software	OSW Aligner System 3-D software performs the following operations: • Produce 3D-model file of the PVS impression or digital scan. • Identifies the individual teeth that will require treatment (i.e. repositioning). • Creates a treatment plan (i.e. 3-D models that represent the treatment plan). The treating dental practitioner reviews these images using OSWDP software and has the option to reject or request modifications to the set-up prior to approval.	Angel Align System 3-D software performs the following operations: • Produce 3D-model file of the PVS impression or digital scan. • Identifies the individual teeth that will require treatment (i.e. repositioning). • Creates a treatment plan (i.e. 3-D models that represent the treatment plan). The treating dental practitioner reviews these images using iOrtho software and has the option to reject or request modifications to the set-up prior to approval.
Material	0.03” thick, thermoformed polyurethane	0.03” thick, thermoformed polyurethane

Mode of Use	Each appliance is worn by the patient as determined by the dental practitioner, generally 2 weeks prior to being replaced by the next aligner in sequence.	Each appliance is worn by the patient as determined by the dental practitioner, generally 2 weeks prior to being replaced by the next aligner in sequence.
Description of Appliance Application	Removable	Removable
Manufacturing Method	A digital model of the patient's teeth is created from either scanning a PVS impression or directly from an intraoral scan of the patient's teeth. From the digital model, following a dental practitioner's prescription, the software generates model transforms describing the provisional final, treated state and then interpolates a series of model transforms that represent intermediate states of alignment. The resulting computer "setups" relay this information to rapid prototyping machines that produce physical positive models. The aligners are produced by thermoforming on each physical model to fabricate the sequence of aligners.	A digital model of the patient's teeth is created from either CT scanning a PVS impression or directly from an intraoral scan of the patient's teeth. From the digital model, following a dental practitioner's prescription, the software generates model transforms describing the final, treated state and then interpolates a series of model transforms that represent intermediate states of alignment. The resulting computer "setups" relay this information to rapid prototyping machines that produce physical positive models. The aligners are produced by thermoforming on each physical model to fabricate the sequence of aligners.

Technological Characteristic Differences

There are no major technological characteristic differences when comparing the subject device and the predicate device, with only differences in location of manufacturing. Non-clinical performance testing mitigated any concerns regarding this difference.

Non-Clinical Performance Testing

The following non-clinical performance tests were conducted:

Report Name	Standard	Result
OSW OrthoSetup Software Verification Report	N/A (FDA Guidance)	PASS
OSWDP System and Software Verification Report	N/A (FDA Guidance)	PASS
Biocompatibility testing of device – Cytotoxicity	ISO 10993-5	PASS
Biocompatibility testing of device – Irritation	ISO 10993-10	PASS
Biocompatibility testing of device – Sensitization	ISO 10993-10	PASS
Biocompatibility testing of device – Acute Systemic Toxicity	ISO 10993-11	PASS

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 OSW Aligner System to the predicate device.

Bench Testing

Bench testing of the aligners has not been performed due to the difficulty in evaluating this type of dental device in a laboratory setting. There is sufficient information available from the scientific literature and from the predicate device to demonstrate substantial equivalence of the OSW Aligner System to the predicate device.

Substantial Equivalence Conclusion

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Based on the comparison and analysis above, the OSW Aligner System is determined to be substantially equivalent to the referenced primary predicate device.