August 7, 2020

MVP Aligners, LLC
℅ Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K193130
Trade/Device Name: MVP Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: July 28, 2020
Received: August 3, 2020

Dear Prithul Bom:

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.
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)*

k193130

Device Name
MVP Aligner System

Indications for Use *(Describe)*

The MVP Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion in patients with permanent dentition (i.e., all second molars). The MVP Aligners position teeth by way of continuous gentle force.

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 K193130

Date Prepared: September 1, 2019

Submitter: MVP Aligners
5-9 Union Square West, 7th Floor
New York, NY 10003

Contact: Jim Churchill
1 (831) 247-1415

Proprietary Name: MVP Aligner System

Common Name: Sequential Aligners

Classification: 21 CFR 872.5470: Orthodontic plastic bracket; Class II
Predicate Device Ormco K182826
Reference Device(s): 3Shape K180941, Clearcorrect K113618

Device Description: The MVP Aligner system is a prescription (Rx) device comprised of a series of dentist prescribed clear, biocompatible, plastic shells that fit over the teeth designed to incrementally improve malocclusion by providing progressive force and moving patient dentition from an initial condition to a preferred corrected condition. After a scan or physical impression of the patient's teeth is taken by or under the direct supervision of the patient's orthodontically trained dentist, each aligner in the sequential set is created by a trained technician utilizing Ortho System software (K180941) according to the orthodontic screening and tooth movement recommendations provided by the same prescribing orthodontically trained dentist. The recommendations are patient specific and can only be relied upon for an individual patient for whom the device is prescribed. Furthermore, the orthodontically trained dentist reviews and approves the model scheme before the molds are produced. Once approved, the trays which are formed of clear, thin, thermoformed plastic are fabricated.

The indirect fabrication process involves a 3D print of a plastic model representing the patient specific upper and lower dentition of the patient's jaw. The models are cured. Biocompatible plastic sheets are thermoformed over the cured models with pressure and heat, marked with a patient identifier on the occlusal surface, and trimmed in a 5-axis CNC machine. The aligner containing an individualized trim line is polished, cleaned, sorted and packaged with a UDI.

MVP Aligners are provided non-sterile and are completely removable by the patient. Once approved, the trays are sent back to the orthodontically trained dentist who then provides them to the patient, in sequential stages confirming fit and design. The orthodontically trained dentist monitors treatment from the delivery of the first to final aligner.

Indications for use / Intended use: The MVP Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion in patients with permanent dentition (i.e., all second molars). The MVP Aligners position teeth by way of continuous gentle force.

Clinical Data: 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. There is sufficient information available from scientific literature to support safety and efficacy. Therefore, clinical testing was not necessary to demonstrate substantial equivalence of the MVP Aligners to the predicate device.

Manufacturing/Mechanical: The material properties of thermoplastic polyurethane have been received from and demonstrated by the manufacturer through biocompatability, crack resistance and stress relaxation testing and have been proven effective with over eight years of clinical use in the clear aligner field. Validation and verification tests confirmed the accuracy of each step of the manufacturing process and that the clarity and fit met the predetermined requirements.

	MVP Aligner System	Ormco (predicate) (K182826)	ClearCorrect (reference) (K113618)
Indications for Use	The MVP Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion in patients with permanent dentition (i.e., all second molars). The MVP Aligners position teeth by way of continuous gentle force.	The OrmcoTM SparkTM Aligner System is indicated for the alignment of teeth during orthodontic treatment of malocclusion in patients with permanent denitition (i.e., all second molars). The OrmcoTM SparkTM Aligner System positions teeth by way of continuous gentle force.	ClearCorrectSystem is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The ClearCorrect System positions teeth by way of continuous gentle force.
Product Code	NXC	NXC	NXC
Classification	872.5470	872.5470	872.5470
Material	Thermoplastic polyurethane	Thermoplastic Polyurethane	Thermoplastic polyurethane
Mode of Action	Continuous gentle force applied to teeth to achieve movement. Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Continuous gentle force applied to teeth to achieve movement
Patient Removable	Yes	Yes	Yes
Duration of use	20-22 hours/day	20-22 hours/day	20-22 hours/day
Biocompatability	cytotoxicity (ISO 7405 6.2, 6.3 and ISO 10993-5), delayed-type hypersensitivity (ISO 10993-10), irritation (ISO 10993-10), acute systems toxicity (ISO 10993-11), subchronic systemic toxicity (ISO 10993-11) and genotoxicity (ISO 10993-3)	ISO 7405:2008 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry	ISO 10993-5 Cytotoxicity, ISO 10993-10 Intracutaneous reactivity, oral mucosa irritation test, maximum test for delayed type hypersensitivity
OTC or Rx	Rx	Rx	Rx

Non-clinical data

Biocompatatility: Biocompatibility of the base plastic was evaluated by the manufacturer according to ISO 10993-1, including cytotoxicity (ISO 7405 6.2, 6.3 and ISO 10993-5), delayed-type hypersensitivity (ISO 10993-10), irritation (ISO 10993-10), acute systems toxicity (ISO 10993-11), subchronic systemic toxicity (ISO 10993-11) and genotoxicity (ISO 10993-3).

Summary of Substantial Equivalence: The MVP Aligner system has the identical indications for use as the Ormco aligner system (K182826). The MVP Aligner, has the same mode of action, duration of use, is similarly patient removable, and utilizes the same base material, which has passed biocompatibility testing both in its native form and as a finished medical device, as was cleared by Ormco (K182826) and Clearcorrect (K113618). Based on a comparison of these factors, we believe that the MVP Aligner system is substantially equivalent to the predicate.