March 20, 2020

Motor City Lab Works
% Chris Brown
Manager
Aclivi, LLC
6455 Farley Road
Pinckney, Michigan 48169

Re: K191838
Trade/Device Name: Clearform Aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: February 10, 2020
Received: February 18, 2020

Dear Chris Brown:

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,

for Srinivas “Nandu” 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)*
K191838

Device Name
ClearForm Aligners

Indications for Use *(Describe)*
ClearForm Aligners are indicated for the alignment of teeth in patients with permanent dentition (i.e. all second molars) during orthodontic treatment of malocclusions. The aligners position teeth by way of continuous gentle forces.

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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K191838
510(k) Summary
Motor City Lab Works
ClearForm Aligners

ADMINISTRATIVE INFORMATION

Manufacturer Name	Motor City Lab Works 2200 Holland St Birmingham, Michigan 48009 USA Telephone: +1 (248) 250-9519 Fax: n/a
Official Contact	Dr. Christian Groth, President Telephone: +1 (248) 250-9519
Email:	Info@motorcitylabworks.com
Date Submitted:	2/10/2020

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	ClearForm Aligners
Common Name:	Aligners, sequential
Classification Name:	Orthodontic Plastic Bracket
Classification Regulations:	21 CFR 872.5470
Device Class:	Class II
Product Code:	NXC
Review Panel:	Dental
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

PREDICATE DEVICE INFORMATION

The devices within this submission are substantially equivalent in indications, intended use and design principles to the following predicate device:

510(k)	Predicate Device Name	Company Name
K180241	Twin Aligner	Ortho Caps GmbH
	Reference Device Name	
K180941	Ortho System	3Shape A/S
K062828	Essix	Dentsply

DEVICE DESCRIPTION

ClearForm Aligners consist of a series of customized removable plastic orthodontic appliances which sequentially reposition teeth by way of continuous gentle force.

A digital or traditional mold impression of the patient's teeth is provided by a dental health professional (e.g. orthodontist or dentist). From the digital data created of the patient's teeth, specialized

orthodontic CAD/CAM software is used to develop an orthodontic treatment plan. Using the software dental technicians produce a series of intermediate digital models corresponding to each stage of treatment, gradually aligning the patient's teeth according to the dental health professional's prescriptions.

The specialized orthodontic treatment planning software has a 510k clearance for the intended use under FDA Classification Product Code PNN, regulation 872.5470.

The prescribing doctor reviews and approves the treatment plan before the models/molds are produced.

Once approved, physical models are produced from the digital model files. The aligner trays are formed over the physical models by using thermal forming equipment and a thermoplastic sheet. The aligner trays are sent to the dental health professional who then delivers them to the patient, confirming fit and design. Over a period of time, additional trays are provided sequentially to the patient by the dental health professional to gradually move the teeth to the desired position. The dental health professional monitors treatment from the moment the first aligner is delivered to when the final aligner is delivered and treatment complete. The aligners are held in place by pressure and can be removed by the patient at any time.

INDICATIONS FOR USE

ClearForm Aligners are indicated for the alignment of teeth in patients with permanent dentition (i.e. all second molars) during orthodontic treatment of malocclusions. The aligners position teeth by way of continuous gentle forces.

EQUIVALENCE TO MARKETED DEVICE

The Subject device is highly similar to the Predicate device with respect to Indications for Use and technological principles. Slight differences in the wording of the Indications for Use only changes the intended use of the Subject device to include patients with permanent dentition (i.e all second molars). The Comparison table below compares parameters and characteristics of the subject device and predicate/reference devices.

Predicate Device Comparison Table

Parameter	**Subject Device** ClearForm Aligner	**Predicate Device** Ortho Caps Twin Aligner K180241
Regulation #	21 CFR 872.5470	21 CFR 872.5470
Device Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket
Product Code	NXC	NXC
Classification	Class II	Class II
Indications for Use	ClearForm Aligners are indicated for the alignment of teeth in patients with permanent dentition (i.e. all second molars) during orthodontic treatment of malocclusions. The aligners position teeth by way of continuous gentle forces.	The Orthocaps TwinAligner® System is indicated for the alignment of teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.
Mode of action	Orthodontic movement occurs through continuous gentle forces applied to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Orthodontic movement occurs through continuous gentle forces applied to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.
Method of use	Each preformed plastic tray is worn in sequence by the patient as prescribed by the dental practitioner.	Each preformed plastic tray is worn in sequence by the patient as prescribed by the dental practitioner.

Parameter	Subject Device ClearForm Aligner	Predicate Device Ortho Caps Twin Aligner K180241
Function of the software	Standard dental software for tooth alignment uses digital scan (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 3D models used to produce thermoformed aligners.	Standard dental software for tooth alignment uses digital scan (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 3D models used to produce thermoformed aligners.
Material	Essix thermoplastic	Thermoplastic
Material Properties	Demonstrates sufficient tensile strength, elasticity, ductility, chemical resistance, and clarity for use as a clear tray aligner	Demonstrates sufficient tensile strength, elasticity, ductility, chemical resistance, and clarity for use as a clear tray aligner.
Design		
Biocompatible	Yes	Yes
OTC or Rx	Rx	Rx
Sterile	Non-sterile	Non-sterile

TECHNOLOGICAL CHARACTERISTICS

The Subject device mechanism of action is identical to the Predicate device and supports a determination of substantial equivalence. The Subject device use of Software is identical to the Predicate device and supports a determination of substantial equivalence. The Subject and Predicate devices are both fabricated of a non-sterile, biocompatible thermoplastic material which supports a determination of substantial equivalence. The Subject device is fabricated of the Reference device material which is indicated for the intended use.

Non-clinical Performance Data

Due to the difficulty in evaluating this type of dental device in a laboratory environment, no direct performance bench testing of the aligners was performed. The use of thermoplastic materials for sequential aligners intended to treat malocclusions have been well documented in scientific literature regarding incremental tooth moving forces.

Software used for treatment planning and creation of models/casts for ClearForm Aligners is manufactured by 3Shape A/S under the name Ortho System. It has a 510(k) clearance (K180941) under the PNN product code and is indicated for the intended use.

An internal manufacturing validation was performed to demonstrate the dimensional accuracy of the manufacturing process for ClearForm Aligners. Three critical aspects of the manufacturing process were assessed for accuracy: digital dentition models from treatment planning, 3D printed molds, and the final thermoformed aligners.

Independent 3rd party reverse engineering/inspection software was used to perform point-to-point and critical displacement measurements.

Translational measurements were within 0.150 mm (150 microns) of the target input value, the predefined tolerance of the manufacturing process. There were no significant differences in the

difference in the intended and measured values observed from any of the groups. This test has met the pre-established acceptance criteria to demonstrate dimensional accuracy.

An additional qualitative assessment of device fit was performed meeting the acceptance criteria.

The material used for ClearForm Aligners has a 510(k) clearance (K062828) for use as an aligner material. Biocompatibility testing for the aligner material, the only patient contacting material, has been conducted by the 510(k) holder in accordance with International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".

Additional cytotoxicity testing according to ISO 10993-5:2009 was performed on the final, finished Subject device.

CLINICAL TESTING

Clinical performance data was not provided for ClearForm Aligners.

CONCLUSION

Based on similarities in Indications for Use and technology, as well as non-clinical performance testing, we believe that ClearForm Aligners are substantially equivalent to the Orthocaps TwinAligner® System.