May 9, 2019

Voodoo Manufacturing, Inc.
% Mark Job
Official Correspondent
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K190948
Trade/Device Name: Magic Clear Aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: April 9, 2019
Received: April 11, 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/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,

for Malvina Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

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)*
K190948

Device Name
Magic Clear Aligners

Indications for Use *(Describe)*
Magic Clear Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusions 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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K190948

510(k) Summary
Voodoo Manufacturing, Inc
Magic Clear Aligners
4/1/2019

5.1 ADMINISTRATIVE INFORMATION

Manufacturer Name	Voodoo Manufacturing, Inc 361 Stagg Street #408 Brooklyn, NY 112062 USA Telephone: +1 (646) 854-4173 Fax: n/a
Official Contact	Max Friefeld, CEO
Email:	max@voodoomfg.com

5.2 DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Magic Clear Aligners
Common Name:	Aligners, sequential
Classification Name:	Orthodontic Plastic Bracket
Classification Regulations:	21 CFR 872.5470
Device Class:	Class II
Product Code:	NXC
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

5.3 PREDICATE DEVICE INFORMATION

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

510(k)	Predicate Device Name	Company Name
K180241	Twin Aligner	Ortho Caps GmbH

510(k)	Reference Device Name	Company Name
K180941	Ortho System	3Shape A/S
K113618	ClearCorrect System	ClearCorrect LLC

5.4 DEVICE DESCRIPTION

Magic Clear Aligners consist of a series of custom-made 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 treatment plans. Using the software, dental technicians design a series of intermediate models corresponding to each stage of treatment, gradually realigning the patient's teeth according to the dental health professional's prescription.

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

Once approved, the specialized orthodontic software is used to generate standard format 3D files which are used to physically produce each model/mold in the treatment plan for aligner fabrication. Voodoo Manufacturing produces the aligner trays by thermal forming a plastic sheet over each model in the treatment plan. 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.

The specialized orthodontic treatment planning software has a 510k clearance for the intended use under FDA Classification Product Code PNN, regulation 872.5470. The manufacturing process has been internally validated by Voodoo Manufacturing, Inc.

The technology is identical to that used by the Predicate device, Ortho Caps Twin Aligner (K180241) and a number of other sequential aligner systems currently being legally marketed.

5.5 INDICATIONS FOR USE

Magic Clear Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.

5.6 EQUIVALENCE TO MARKETED DEVICE

The Subject device is substantially equivalent to the predicate device with respect to Indications for Use and technological principles. The Comparison table below compares parameters and characteristics of the subject device and predicate/reference devices.

Predicate Device Comparison Table

Parameter	**Subject Device** Magic Clear 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	Magic Clear Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusions 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.
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	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

Parameter	Subject Device Magic Clear Aligner	Predicate Device Ortho Caps Twin Aligner K180241
	dental practitioner approves the treatment plan, the software converts the files to produce the series of 3D models used to produce thermoformed aligners.	practitioner approves the treatment plan, the software converts the files to produce the series of 3D models used to produce thermoformed aligners.
Material	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

5.7 TECHNOLOGICAL CHARACTERISTICS

Orthodontic tooth movement occurs through forces applied to the teeth by the appliance as each tooth follows the predetermined displacement based on a dental health professional's prescription. 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.

5.8 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 Magic Clear 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.

A manufacturing validation was performed to demonstrate the dimensional accuracy of the manufacturing process for Magic Clear 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.

All translational measurements were within 0.15 mm of the target input value, the predefined tolerance of the manufacturing process. There were no statistical 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.

5.9 CLINICAL TESTING

The performance of sequential aligners in the clinical environment has been well established since the first such devices were cleared by the FDA in 1998 under product code NXC. Therefore, there no clinical testing is required to support Magic Clear Aligners, as the Indications for Use is equivalent to the Predicate device, which also was not subject to clinical testing. No clinical data is included in this submission.

5.10 BIOLOGICAL TESTING

Biocompatibility testing for the aligner material, the only patient contacting material, was conducted in accordance with International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". The results of the tests satisfy the requirements of the study protocols and comply with ISO 10993-1 for the intended use.

The following biological tests were performed:

Biological Endpoint	Relevant Standard
Cytotoxicity	ISO 10993-5:2009
Sensitization	ISO 10993-10:2010
Irritation	ISO 10993-10:2010
Subacute/SubChronic Toxicity	ISO 10993-11:2006
Genotoxicity	ISO 10993-3:2014

5.11 CONCLUSION

Indications for Use statement for the Subject and Predicate devices is identical.

The Technological Characteristics, Materials, Prescription Use and Non-sterile status of the Subject device is identical to the Predicate device.

The use of Software to produce the Subject and Predicate devices is identical.

Overall, the Magic Clear Aligners are substantially equivalent to the Predicate device.