October 26, 2021

Oral Image, Inc
% Chris Brown
Manager
Aclivi, LLC
3250 Brackley Drive
Ann Arbor, Michigan 48105

Re: K211537
Trade/Device Name: QuickAligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: September 21, 2021
Received: September 27, 2021

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,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211537

Device Name
QuickAligners

Indications for Use *(Describe)*
Oral Image QuickAligners are indicated for the alignment of teeth in patients with permanent dentition (i.e. all second molars) during orthodontic treatment of malocclusion. QuickAligners 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
K211537
Oral Image, Inc
QuickAligners
9/21/2021

ADMINISTRATIVE INFORMATION

Submitter/Manufacturer Name:	Oral Image, Inc 6440 Lusk Blvd Suite D101 San Diego, CA 92121
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Official Contact:	Vinh Lam, CRO
Email:	vinh.lam@oralimage.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	QuickAligners
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 Products Panel
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
K202857	ClearPath Aligner	ClearPath Orthodontics, Ltd

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

DEVICE DESCRIPTION

The Oral Image QuickAligners are a series of prescription-only clear plastic removable aligners intended to incrementally move a patient's teeth from an initial state to a different end state using a software-generated sequence of intermediate states.

Based on a clinician's prescribed treatment plan, each aligner in the set is used for the specified period of time to exert gentle force to achieve progressive realignment of the teeth until the final correction has been achieved. Standard treatment time for each aligner tray is 2-3 weeks, worn by patient for 22 hours per day.

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. Oral Image, Inc produces the aligner trays by thermoforming 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 in sequential stages. Additional trays are used sequentially by the patient 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 finished and treatment complete. The aligners are held in place by pressure and can be removed by the patient at any time.

The technology is the same as that used by the Predicate device, ClearPath Aligner (K202857) and a number of other sequential aligner systems currently being legally marketed.

INDICATIONS FOR USE

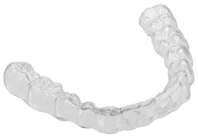
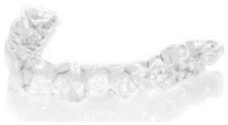
Oral Image QuickAligners are indicated for the alignment of teeth in patients with permanent dentition (i.e. all second molars) during orthodontic treatment of malocclusion. QuickAligners position teeth by way of continuous gentle force.

EQUIVALENCE TO MARKETED DEVICE

Overall, 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** QuickAligners Oral Image, Inc	**Predicate Device** ClearPath Aligner ClearPath Orthodontics, Ltd K202857
Regulation #	21 CFR 872.5470	21 CFR 872.5470
Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket
Product Code	NXC	NXC
Classification	Class II	Class II
Indications for Use	Oral Image QuickAligners are indicated for the alignment of teeth in patients with permanent dentition (i.e. all second molars) during orthodontic treatment of malocclusion. QuickAligners position teeth by way of continuous gentle force.	The ClearPath Aligner is a series of clear, lightweight, plastic appliances indicated for the correction of dental malocclusion in patients with permanent dentition (i.e. all second molars). The ClearPath Aligner positions teeth by way of continuous gentle force.
Mode of Action / Use	Based on a clinician's prescribed treatment plan, each aligner in the set is used for the specified period of time to exert gentle force to achieve progressive realignment of the teeth until the final correction has been achieved. Standard treatment time for each aligner tray is 2-3 weeks, worn by patient for 22 hours per day.	Based on a clinician's prescribed treatment plan, each aligner in the set is used for the specified period of time to exert gentle force to achieve progressive realignment of the teeth until the final correction has been achieved. Standard treatment time for each aligner tray is 2-3 weeks, worn by patient for 22 hours per day.
Software used	Yes, for treatment planning and 3D printing of models.	Yes, for treatment planning and 3D printing of models.
3D Software Description	It is used for management of 3D scanned orthodontic models, orthodontic diagnosis by measuring, analyzing, inspecting and visualizing 3D scanned orthodontic models, virtual planning of orthodontic treatments by	It is used for management of 3D scanned orthodontic models, orthodontic diagnosis by measuring, analyzing, inspecting and visualizing 3D scanned orthodontic models, virtual planning of orthodontic treatments by simulating

Parameter	Subject Device QuickAligners Oral Image, Inc	Predicate Device ClearPath Aligner ClearPath Orthodontics, Ltd K202857
	simulating tooth movements, and design of orthodontic appliances based on 3D scanned orthodontic models.	tooth movements, and design of orthodontic appliances based on 3D scanned orthodontic models.
Material	Thermoformed plastic	Thermoformed plastic
Appliance Application	Removable	Removable
Design		
Biocompatible	Yes	Yes
OTC or Rx	Rx	Rx
Sterile	Non-sterile	Non-sterile
Validation Testing	Yes, performed.	Yes, performed.

The wording of the Indications for Use of the Subject device is highly similar to that of the Predicate device, differing slightly in wording and device name. These differences do not change the intended use of the Subject or Predicate devices to be used in the alignment of teeth during orthodontic treatment of malocclusion and supports a finding of substantial equivalence.

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 mode of action and use is the same as the Predicate device and supports a determination of substantial equivalence.

The Subject and Predicate devices both use 510(k)-cleared Software in treatment planning process which supports a determination of substantial equivalence. The Reference device software has been validated for use with the Subject device.

The Subject and Predicate devices are both fabricated of a non-sterile, biocompatible thermoplastic material which supports a determination of substantial equivalence.

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 to an established standard 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.

Aligner sheet physical properties testing was conducted and provided for review by the material manufacturer.

Bench testing was performed to validate the manufacturing process. An assessment was performed to validate aligner fit and performance.

Biocompatibility testing for the aligner 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.

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 Oral Image QuickAligners, 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.

CONCLUSION

Overall, the Indications for Use statement for the Subject and Predicate devices are substantially equivalent.

Overall, the Technological Characteristics, Materials, Prescription Use and Non-sterile status of the Subject device are substantially equivalent to the Predicate device. The use of Software to produce the Subject and Predicate devices is substantially equivalent. A manufacturing validation has been done to demonstrate the manufacturing process works as intended. The fit/performance validation has been performed to demonstrate the device and manufacturing process are suitable for intended use.

Overall, the Oral Image QuickAligners are substantially equivalent to the Predicate device.