Ortho Caps GmbH
% Angelica Ayala
Regulatory Affairs Specialist
RMO, Inc.
650 W. Colfax Ave
Denver, Colorado 80204

September 28, 2018

Re: K180241
Trade/Device Name: Orthocaps Twinaligner®
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: August 28, 2018
Received: August 29, 2018

Dear Angelica Ayala:

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,

Mary S. Runner -S3

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K180241

Device Name
Orthocaps TwinAligner® System

Indications for Use *(Describe)*
The Orthocaps TwinAligner® System is 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

1. **Date Prepared:** September 27, 2018

2. **Submitter Information:**

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3. **Submission Correspondent:**

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4. **Device Information:**

Trade/Proprietary Name: Orthocaps TwinAligner® System
Common Name: Aligner, Sequential
Classification Name: Orthodontic plastic bracket
Classification Regulation: 872.5470
Device Classification: Class II
Product Code: NXC

5. **Predicate Devices:**

Invisalign® System	Primary Predicate	K081960	Align Technology, Inc
ClearCorrect System	Reference Predicate	K113618	ClearCorrect LLC
3Shape Ortho System™	Reference Predicate	K152086	3Shape A/S

6. **Device Description:**

Orthocaps TwinAligner® System consists of a series of custom made removable clear plastic orthodontic aligners that sequentially positions teeth by way of continuous gentle force.

An electronic scan or mold impression of the patient's teeth in an untreated state is provided by a dental or orthodontic professional. From the digital scan, Orthocaps technicians design a series of intermediate models corresponding to each stage of treatment intended to gradually realign the patient's teeth in accordance with the physician's prescription using a standard dental software used for tooth alignment. The prescribing physician reviews and approves the model scheme before the molds are produced. Once approved, Orthocaps produces the aligner trays formed from clear, thin thermoformed

plastic. The trays are sent back to the physician for patient fit and treatment. Additional trays are provided sequentially to gradually move the target teeth to the designed position, which is monitored throughout treatment by the physician. The aligner trays are held in place by pressure and can be removed by the patient at any time. Specialized orthodontic CAD/CAM software will be used to develop the treatment plans and to produce standard 3D printed files that will facilitate the manufacturing of each sequential aligner in the treatment plan. The software application used for the manufacturing validation for this subject device is the 3Shape reference predicate.

7. Intended Use:

The Orthocaps TwinAligner® System is indicated for the alignment of teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.

8. Substantial Equivalence:

The Orthocaps TwinAligner® System is substantially equivalent to the predicate devices with respect to indications for use, technological characteristics, principles of operation, and materials, as demonstrated in the comparison below:

Element	Subject Device	Primary Predicate	Reference Predicate
Device Name	Orthocaps TwinAligner® System	Invisalign® System	ClearCorrect
Manufacturer	Ortho Caps GmbH	Align Technology, Inc.	ClearCorrect LLC
510(k) Number	K180241	K081960	K113618
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	21 CFR 872.5470
Device Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket
Device Classification	Class II	Class II	Class II
Product Code	NXC	NXC	NXC
Indications for use	Orthocaps TwinAligner® System is indicated for the alignment of teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.	The Invisalign System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.	ClearCorrect System 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.
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	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	Each preformed plastic tray is worn in sequence by the patient as prescribed by the dental practitioner
Software Description for tooth movement	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.	A digital 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.	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	Thermoplastic	Thermoplastic	Thermoplastic
OTC or Rx	Rx	Rx	Rx
Sterilization	No	No	No
Design			

The Indications for Use of the subject device are essentially the same as currently marketed predicate devices. The verbiage of the Indications of Use of the subject device is slightly different than predicate devices; however, these slight differences do not affect the intended therapeutic treatment of malocclusions as compared to the predicates.

The technological characteristics of the subject device regarding the design, materials, and treatment of malocclusions through sequential thermoplastic aligners follow the same technological principles as predicate devices. While there are different trays worn during daytime and nighttime, these slight differences from predicate devices do not alter the intended therapeutic treatment of malocclusions using clear aligners.

The mode of action for the subject device is fundamentally the same to predicate devices and supports the determination of substantial equivalence. Orthodontic tooth movement

occurs through continuous gentle forces applied to dentition using sequential removable thermoplastic aligners.

The use of dental software to translate tooth movements in developing the model scheme in the subject device is essentially the same to predicate devices. The subject and reference predicate devices allow the dental practitioner to review and approve the model scheme before aligner fabrication.

9. Non-Clinical Performance Data

Biocompatibility Testing:
The biocompatibility testing for the device was conducted in accordance to ISO 10993-1 and its applicable parts. The results of the testing satisfy the requirements of the study protocols and comply with ISO 10993-1 for the intended use. The results of the studies further support a determination of substantial equivalence. The battery of testing included the following tests:

Test	**Standard**	**Result**
Cytotoxicity	ANSI/AAMI/ISO 10993-5	PASS
Irritation	ISO 10993-10	PASS
Sensitization	ISO 10993-10	PASS

Verification and Validation Testing:
Results of verification and validation testing demonstrate device conformity with pre-established specifications using a physical model cast impression. There was no measurable deviation between physical and digital models established in the process workflow.

Bench testing was not performed due to the difficulty in evaluating this type of dental device in a laboratory setting. The use of thermoplastic materials for sequential aligners intended to treat malocclusions have been well documented in scientific literature regarding incremental tooth moving forces.

10. Clinical Performance Data:
Clinical data was not included in this submission.

11. **Conclusion**
The Orthocaps TwinAligner® System has substantially equivalent Indications for Use and technological characteristics to the previously cleared predicate devices.

The conclusions drawn from the data included in this submission demonstrate that Orthocaps TwinAligner® System is substantially equivalent to the predicate devices in indications for use, design, technological characteristics, mode of action, method of use, performance, materials, and biocompatibility.