February 26, 2021

Aso International Manila, Inc.
% Giselle Zhang
Regulatory Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K201104
Trade/Device Name: AsoAligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: January 21, 2021
Received: January 21, 2021

Dear Giselle Zhang:

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 Adjodha
Assistant 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)*
K201104

Device Name
AsoAligner

Indications for Use *(Describe)*
AsoAlignerTM 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). AsoAligner™ is intended for minor anterior tooth movement by applying continuously gentle force. AsoAligner™ is for prescription only use.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

ASOALIGNER™

1. Submission Sponsor

ASO INTERNATIONAL MANILA, INC.
Atlantica Bldg. 5, Block 12, Phase 1, South Avenue
Cavite Economic Zone, Rosario
Cavite
Philippine
Contact: Hiromichi Takahashi
Title: International Marketing Manager

2. Submission Correspondent

Emergo Global Consulting, LLC
2500 Bee Cave Road
Building 1, Suite 300
Austin, TX 78746
Office Phone: (512) 327-9997
Email: LST.AUS.ProjectManagement@ul.com
Contact: Giselle Zhang
Title: Regulatory Consultant

3. Date Prepared

April 10th 2020

4. AsoAligner™ Identification

Trade/Proprietary Name:	AsoAligner™
Common/Usual Name:	Aligner, Sequential
Classification Name:	Orthodontic plastic bracket
Regulation Number:	872.5470
Product Code:	NXC
Class:	2
Classification Panel:	Dental

5. Legally Marketed Predicate Device

Predicate name:	eCligner®
510(k) number:	K143499

Manufacturer: eClear International Co., Ltd.

The eCligner®, is a transparent and removable orthodontic appliance and digitally-made Clear Aligner by the 3D printing, and printing the completed setup data into a series of plastic models with simple stamping procedure (Vacuum forming).

During one individual step of treatment, three different layer thickness of eCligner® are worn in weekly intervals. The applied layer thicknesses are 0.5 mm (soft), 0.62 mm (medium) and 0.75 mm (hard).

For eCligner®, there's also a Ultra Hard aligner which the layer thickness is 1.00 mm, and is used only for the patient with Bruxism (Teeth Grinding) since the aligner can be broken while the patient grinds their teeth unintentionally.

6. Indication for Use Statement

AsoAligner™ 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). AsoAligner™ is intended for minor anterior tooth movement by applying continuously gentle force. AsoAligner™ is for prescription only use.

7. AsoAligner™ Description

AsoAligner™ consists of a series (soft, medium, and hard) of patient-specific transparent thermoplastic removable aligners, intended to be used to replace the traditional lingual/labial orthodontic braces for the treatment of tooth malocclusion in patients with permanent dentition, and by applying continuous gentle force to progressively position the teeth.

Each aligner is patient-specific and should be used only by the person for whom the aligners were prescribed. AsoAligner™ is provided non-sterile and can be removed by the patient at any time. During clinical examination to a patient with permanent dentition, a dental health professional determines the appropriateness for prescribing the AsoAligner™ to patient based on an assessment of the patient's teeth. The dental health professional takes an impression of the patient's dentition and sends it together with the treatment plan prescription containing the course of treatment to ASO. The patient's impression is then used to produce a series of dental arch setup models using 3Shape's Ortho Analyzer (K180941) based on the instructions found in the treatment plan prescription. The dental health professional will review and approve, or reject (and request for treatment modifications if rejected) the dental arch setup. The validated dental arch setups are then used as a mold to produce the sequential AsoAligner™. The sequential AsoAligner™ is sent back to the dental health professional who then provides them to the patient, confirming fit and design. The dental health professional monitors the patient's treatment from the moment the first aligner is delivered to when the final aligner is delivered. AsoAligner™ is held in place by applying pressure to the patient's teeth.

8. Substantial Equivalence Discussion

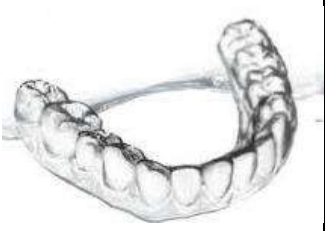
The following table compares the ASOALIGNER™ to the predicate eCligner© with respect to indications for use, principle of operation, technological characteristics, and materials, and forms the basis for the

determination of substantial equivalence. The subject AsoAligner™ does not raise any new questions of safety or effectiveness as compared to the predicate eCligner©.

Table 5A – Comparison of Characteristics

Attribute	**AsoAligner™**	**eCligner© K143499**	**Comparison**
Manufacturer	ASO INTERNATIONAL MANILA, INC	eClear International Co., Ltd.	N/A
Product Code	NXC	NXC	Same
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	Same
Indications for Use	AsoAlignerTM 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). AsoAligner™ is intended for minor anterior tooth movement by applying continuously gentle force. AsoAligner™ is for prescription only use.	The eCligner® is a series of transparent removable orthodontic appliances indicated for the correction of dental malocclusion. The eCligner® is intended to position teeth by way of continuous gentle force.	Similar The verbiage is different, the intended use is the same for both device.
Mechanism of Action	Applying continuous gentle force to move the teeth	Applying continuous gentle force to move the teeth	Same
Layer Thickness	Soft (0.5 mm)	Soft (0.5 mm)	Similar The soft layer of both aligners are the same. As for the Medium and Hard layer, the differences are within the acceptable range, which 3% for the Medium and 6% for the Hard, the differences this small will no influence on the safety and effectiveness of the device.
	Medium (0.6 mm)	Medium (0.62 mm)	
	Hard (0.8 mm)	Hard (0.75 mm)	
	N/A	Ultra Hard (1 mm)	
Prescription Steps	Soft (7-10 days)	Soft (1 Week)	Similar

	Medium (7-10 days)	Medium (1 Week)	The prescriptions steps are almost the same, in order to enforce the outcome of using the aligner, ASO suggest to change to next step within 10 days, and 7 days is also one of ASO's recommendation, hence the differences will not raise any new risks related to safety and effectiveness.
	Hard (10-14 days)	Hard (1 Week)	
Duration of Wear	At least 20-22 hours	17 hours a day	Similar The instructions is recommended by ASO based on the typical use of such devices type. Hence the differences will not raise any new risks related to safety and effectiveness.
Material	Thermoplastic	Thermoplastic	Same
Sterile	Non-Sterile	Non-Sterile	Same
Single-Use	Single User Use	Single User Use	Same

Attribute	**AsoAligner™**	**eCligner© K143499**	
Shelf Life	N/A	N/A	Same
Design	Transparent, 3D print, and vacuum forming.	Transparent, 3D print, and vacuum forming.	Same
Picture			Same
Complies with ISO 10993-1	Yes	Yes	Same

Comparison Discussion

The AsoAligner has the same intended use and the same or similar technological characteristics and functionality as the predicate, and therefore is substantially equivalent to the predicate device. The minor differences do not raise new questions of safety and effectiveness as compared to the predicate device.

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of ASOALIGNER™ and to show substantial equivalence to the predicate AsoAligner™, ASO completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the AsoAligner™ are met. The ASOALIGNER™ passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate AsoAligner™:

- ISO 10993-1 Fourth Edition 2009-10-15 Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process [Including: Technical Corrigendum 1 (2010)] – Evaluated
- ISO 10993-3 Third Edition 2014-10-1 Biological Evaluation Of Medical Devices - Part 3: Tests For Genotoxicity, Carcinogenicity And Reproductive Toxicity - Passed
- ISO 10993-5 Third Edition 2009-06-01 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity - Passed
- ISO 10993-10 Third Edition 2010-08-01 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization - Passed

- ISO 7405 Third Edition 2018-10 Corrected Version 2018-12 Dentistry - Evaluation Of Biocompatibility Of Medical Devices Used In Dentistry - Passed
- ASTM F1886/F1886M-16 Standard Test Method For Determining Integrity Of Seals For Flexible Packaging By Visual Inspection - Passed
- ASTM F2475-11 Standard Guide For Biocompatibility Evaluation Of Medical Device Packaging Materials - Passed
- ASTM D4169-16 Standard Practice For Performance Testing Of Shipping Containers And Systems - Passed
- ISO 10993-18 Biological Evaluation of Medical Device – Part 18: Chemical Characterization of Materials. - Passed
- EN ISO 14971:2012, Medical devices. Application of risk management to medical devices -Evaluated

10. Statement of Substantial Equivalence

The ASOALIGNER™ has the same intended use as the eClingner©, and the same or similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and effectiveness. Therefore, the ASOALIGNER™ is substantially equivalent to the predicate AsoAligner™.