March 12, 2024

Laon Medi Inc.
Mina Yun
Quality Management Representative
404, Bundang Techno Park B, 723, Pangyo-ro, Bundang-gu
Seongnam-si, Gyeonggi-do 13511
SOUTH KOREA

Re: K232564
Trade/Device Name: Align Studio
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN, LLZ
Dated: January 12, 2024
Received: January 12, 2024

Dear Mina Yun:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Michael E. Adjodha, MChE, RAC, CQIA
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)*
K232564

Device Name
Align Studio

Indications for Use *(Describe)*
The Align Studio is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options based on 3Dmodels of the patient's dentition before the start of an orthodontic treatment.
The use of the Align Studio requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.

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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K232564

510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

August 24, 2023

2. Submitter's Information & Contact Person [21 CFR 807.92(a)(1)]

- Name of Manufacturer: LAON MEDI Inc.
- Address: 404, Bundang Techno Park B, 723, Pangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, 13511 Republic of Korea / Tel: 031-8017-7145
- Contact Name: Mina Yun
- Telephone No.: +82 10 3953 4808
- Fax No.: +82 31 701 8863
- Email Address: may@laon-medi.com

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade name: Align Studio

Classification Description	21 CFR Section	Product Code
Orthodontic Software	872.5470	PNN
System, Image Processing, Radiological	892.2050	LLZ

As stated in 21 CFR, parts 872.5470 and 892.2050, this generic types of devices has been classified as Class II.

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4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow:

Predicate device #1

- 510(k) Number: K180941
- Applicant: 3Shape A/S
- Classification Name: Orthodontic Software
- Trade Name: Ortho System

Predicate device #2

- 510(k) Number: K171122
- Applicant: Dentsply Sirona
- Classification Name: Orthodontic Software
- Trade Name: CEREC Ortho Software

5. Description of the Device [21 CFR 807.92(a)(4)]

Align Studio is a PC-based software that sets up virtual orthodontics via digital impressions. It automatically segments the crown and the gum in a simple manner and provides basic model analysis to assist digital orthodontic procedures.

6. Indications for Use [21 CFR 807.92(a)(5)]

The Align Studio is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Export of Models, Indirect Bonding Transfer Media) based on 3Dmodels of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives.

The use of the Align Studio requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.

7. Determination of Substantial Equivalence [21 CFR 807.92(a)(6) and 21 CFR 807.92(b)]

There are no significant differences between Align Studio and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to this device in design, function, and technical characteristics.

	Proposed Device	Predicate Device #1	Predicate Device #2	SE Decision
K Number	-	K180941	K171122	-
Manufacturer	LAON MEDI Inc.	3Shape A/S	Dentsply Sirona	-
Model	Align Studio	Ortho System	CEREC Ortho Software	-
Intended Use	The Align Studio is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Export of Models, Indirect Bonding Transfer Media) based on 3Dmodels of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of the Align Studio requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.	Ortho System™ for dental retainers and dental cast for sequential aligners is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options based on 3D models of the patient's dentition before the start of an orthodontic treatment. The use of the Ortho System™ requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.	CEREC Ortho Software is intended for use with image data acquired from handheld intra oral 3D cameras and desktop laboratory scanners to create 3D virtual models to be used for data acquisition and modeling analysis for orthodontic patients and conditions. The CEREC Ortho Software 3D model data can be exported to orthodontic design software to aid in the design of orthodontic appliances.	Same

Module	Imports scanned image of patient	Imports scanned image of patient	Imports scanned image of patient	Same
	Stand-alone software module	Stand-alone software module	Stand-alone software module	
	Can be used to design dental casts	Can be used to design dental casts	Can be used to design dental casts	
	Useful for diagnosis, treatment planning, and CAD design	Useful for diagnosis, treatment planning, and CAD design	Useful for diagnosis, treatment planning, and CAD design	
	Virtual planning of tooth movement	Virtual planning of tooth movement	Virtual planning of tooth movement	
	Supports .stl files	Supports .stl files	Supports .stl files	
Managing patient and case base data	Creating, editing, deleting and copying patient data	Creating, editing, deleting and copying patient data	Creating, editing, deleting and copying patient data	Same
	Creating, editing, deleting and copying case data	Creating, editing, deleting and copying case data	Creating, editing, deleting and copying case data	
Collection of study material	-	Surface scan for intra-oral scanner	Surface scan for intra-oral scanner	Same
	Surface scan from STL file	Surface scan from STL file	Surface scan from STL file	
	CT image data(DICOM)	CT image data(DICOM)	-	
	-	2D overlay(PNG, JPG, BMP)	-	
	Creation of virtual 3D virtual dental models	Creation of virtual 3D virtual dental models	Creation of virtual 3D virtual dental models	
Alignment of study material	Aligning surface scan or CT image	Aligning surface scan or CT image	-	Same
	Aligning cephalometric images	Aligning cephalometric images		
	-	Alignment of 2D overlays		
	Ability to check/adjust DICOM visibility	Ability to check/adjust DICOM visibility		
Measuring study material	-	2D measurement toolbox	-	Same
	3D measurement toolbox	3D measurement toolbox		

Analyzing study material	Definition of dental Arch shape & length	Definition of dental Arch shape & length	-	Same
	-	Wire length	Wire length	
	Tooth width measurements	Tooth width measurements	-	
	Tooth and gingiva separation/segmentation	-	Tooth and gingiva separation/segmentation	
	Bolton's analysis	Bolton's analysis	Bolton's analysis	
	Space analysis	Space analysis	Space analysis	
	Overjet/overbite	Overjet/overbite	-	
	Occlusal mapping	Occlusal mapping	Occlusal mapping	
Treatment simulation	-	2D simulation	-	Same
	3D simulation	3D simulation		

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Non-Clinical Test Summary [21 CFR 807.92(b)(1)]

1) Software Validation

Align Studio contains Basic Documentation Level software. Software was designed and developed according to a software development process and was verified and validated.

The software information is provided in accordance with FDA guidance: Content of premarket submissions for Device Software Functions, on November 04, 2021.

2) Performance Testing

Through the performance test, it was confirmed that Align Studio meets all performance test criteria and that all functions work without errors. Test results support the conclusion that actual device performance satisfies the design intent and is equivalent to its predicate device.

Clinical Test Summary [21 CFR 807.92(b)(2)]

No clinical studies were considered necessary and performed.

Conclusion [21 CFR 807.92(b)(3)]

Based on a comparison of intended use, indications, principle of operations, features and technical data, and the test results, the Align Studio is found to be as safe and as effective as the predicate device.

Intended use and performance is found to be substantially equivalent to the predicate device, Ortho System (K180941) from 3Shape A/S and CEREC Ortho Software (K171122) from Dentsply Sirona.