July 21, 2020

Diorco Co., Ltd.
% Edward Park
CEO
Radios LLC
4408 Tortuga Ln
McKinney, Texas 75070

Re: K192847
Trade/Device Name: Autolign
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN, LLZ
Dated: June 16, 2020
Received: June 22, 2020

Dear Edward Park:

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
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)*
K192847

Device Name
AUTOLIGN

Indications for Use *(Describe)*
The AUTOLIGN 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 3D models 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 AUTOLIGN 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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510(k) Summary – Traditional 510(k)

Submitter Information

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Contact Person:	HWI JOON PARK, Official Correspondent for DIORCO Co., Ltd.
Date Summary Prepared:	Aug 30, 2019

Device Identification

Trade / Proprietary name:	AUTOLIGN
510(k) Number:	K192847
Regulation Number:	872.5470
Regulation Name:	Orthodontic Plastic Bracket
Classification:	Class II
Product Code:	PNN, LLZ

Predicate Device

Primary predicate device: Ortho System™ (3Shape A/S) - K171634

Reference device: Orchestrate 3D (Orchestrate 3D) - K181112

Reference device: CEREC Ortho Software (Dentsply Sirona) - K171122

Device Description

The AUTOLIGN is stand-alone software which utilizes images of the patient's intraoral anatomy from intra-oral cameras and/or desktop laboratory scanners to create a 3D virtual dental model that can be used in the same manner as a traditional physical dental model. AUTOLIGN facilitates the segmentation and editing of the 3D virtual digital model as well as analysis which can be used in secondary orthodontic treatment planning. The software allows for measurement– including Bolton analyses. The models and analysis produced by the proposed Software can be exported to an orthodontic laboratory or directly to orthodontic

appliance manufacturers for use in orthodontic treatment planning and design of orthodontic appliances. The material used for vacuum pressing (thermoforming) the final device appliances of sequential aligners on the production cast is DURAN®, but those which satisfy all the requirements specified on the Autoling User Manual can also be used.

Indications for Use

The AUTOLIGN 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 3D models 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 AUTOLIGN 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.

Comparison of Indication for Use Statements

The following table compares Indications for Use Statements between the Autolign and the three predicate devices, i.e. Ortho System™, Orchestrate 3D Orthodontic Software, and CEREC Ortho Software. Similar to the other predicate devices, the Autolign is used for managing patient and case base data, collection, alignment, measurement and analysis of study material, treatment of simulation, and virtual appliance design.

AUTOLIGN	Ortho System™	Orchestrate 3D Orthodontic Software	CEREC Ortho Software
The AUTOLIGN 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 3D	Ortho System™ 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 (Custom Metal Bands, Export of Models, Indirect Bonding Transfer	The Orchestrate 3D Orthodontic Software is indicated for use as a front-end software tool for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options, including dental casts, which may be used for sequential aligner trays or retainers.	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

models 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 AUTOLIGN 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.	Media) based on 3D models 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 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.	These applications are based on 3D models 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.se of the Orchestrate 3D 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.	orthodontic design software to aid in the design of orthodontic appliances.

Comparison of Technological Characteristics

Both AUTOLIGN and 3Shape Ortho System™ Software (K171634) are stand-alone software module. They also import digital patient scan files. All the digital data format used for AUTOLIGN are those which the predicate device is already supporting. Like the other predicate devices, AUTOLIGN can be used to design dental cast.With respect to the AUTOLIGN, the 3D virtual model and finalized analysis can be exported to support orthodontic diagnosis and treatment planning of tooth movement**.** It supports STL files.

Comparison Item	AUTOLIGN	Ortho System™	Orchestrate 3D Orthodontic Software	CEREC Ortho Software
Stand-alone software module	O	O	O	O
Imports scanned image of patient	O	O	O	O
Can be used to design dental casts	O	O	O	O
Useful for diagnosis, treatment planning, and CAD design	O	O	O	O

Comparison Item	AUTOLIGN	Ortho System™	Orchestrate 3D Orthodontic Software	CEREC Ortho Software
Virtual planning of tooth movement	O	O	O	Unknown
Supports .stl files	O	O	O	O
Managing patient and case base data				
Creating, editing, deleting and copying patient data	O	O	O	O
Creating, editing, deleting and copying case data	O	O	O	O
Collection of study material				
Surface scan for intra-oral scanner	X	O	O	O
Surface scan from STL file	O	O	O	O
CT image data	X	O (DICOM)	X	X
2D overlay	O (JPG, BMP)	O (PNG, JPG, BMP)	X	X
Creation of virtual 3D virtual dental models	O	O	O	O
Alignment of study material				
Aligning surface scan or CT image	O (but CT image is not available)	O	X	
Aligning cephalometric images	O	O	X	
Alignment of 2D overlays (e.g. ideal arch)	O	O	X	
Ability to check/adjust DICOM visibility	X	O	X	
DICOM scan segmentation	X	X	X	
Measuring study material				
2D measurement toolbox	O	O	X	
3D measurement toolbox	X	O	X	
Analyzing study material				
Definition of dental Arch shape & length	O	O	O	O
Wire length	X	O	X	
Tooth width measurements	O	O	X	O

Comparison Item	AUTOLIGN	Ortho System™	Orchestrate 3D Orthodontic Software	CEREC Ortho Software
Tooth and gingiva separation/segmentation	O	Unknown	Unknown	O
Bolton's analysis	O	O	X	O
Space analysis	O	O	X	O (Nance and Moyer space analysis)
Overjet/overbite	X	O	O	Unknown
Occlusal mapping	O	O	O	O
Treatment simulation				
2D simulation	X	O	X	X
3D simulation	O	O	O	X
Virtual appliance design				
Orthodontic appliance search	O	O	X	X
Orthodontic appliance virtual preparation	O	O	O	X
Orthodontic appliance design	O	O	O	X
Orthodontic appliance export	O	O	O	X

Most comparison items between the subject device and the primary predicate device are identical. However, the other items, which are not identical to the primary predicate device, such as CT image data availability, Ability to check/adjust DICOM visibility, 3D measurement toolbox, Wire length analyzing study material, and 2D treatment simulation, are identical to the other two reference devices.

Non-clinical Tests

The AUTOLIGN underwent software, hardware, integration, verification and validation testing in accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (Issued on May 11, 2005). The software passed the testing and performed per its intended use.

The AUTOLIGN does not include any physical device, accessory, or component with patient contacting intended use. Therefore, no sterilization, or shelf life analyses were included in support of substantial equivalence. However, we tested the compatibility of accessories from other manufacturers such as 3D scanners, CAD/CAM production machines, dental vacuum forming machines, and dental cast material sheets to mitigate concerns with biocompatibility of the output of the proposed device.

Conclusion

Based on comparison of indications for use, scientific concept, technological features, technical data, performance testing, and software validation testing, the AUTOLIGN is found to be as safe and as effective as the primary predicate device. And All the results have been reviewed and approved, showing the AUTOLIGN to be substantially equivalent to the primary predicate device.