June 13, 2023

Shanghai EA Medical Instruments Co., Ltd.
℅ Breanne Butler
Regulatory Affairs Consultant
Prime Path Medtech
1321 Upland Dr. Suite 6792
Houston, Texas 77043

Re: K223518
Trade/Device Name: iOrtho
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN
Dated: May 19, 2023
Received: May 19, 2023

Dear Breanne Butler:

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 -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
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Office of Product Evaluation and Quality
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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)*
K223518

Device Name
iOrtho

Indications for Use *(Describe)*
iOrtho is intended for use as a medical front-end device providing tools for management of orthodontic cases, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Export of Models, Indirect Bonding Transfer Media, Sequential aligners) 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 iOrtho 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 - K223518

A summary of 510(k) substantial equivalence information for this traditional 510(k) in accordance with the requirements of 21 CFR 807.92.

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Date Prepared: June 12, 2023

Trade Name Name: iOrtho

Common Name: Orthodontic plastic bracket (Software)

Classification Name: Orthodontic plastic bracket (Software)

Product Code: PNN

Device Classification: Class II, 21 CFR 872.5470

Predicate Device: 3Shape A/S Ortho System (K171634)

Reference Device: Wuxi EA Medical Instruments Technologies Limited Clear Aligner (K203688)

Reference Device: Dentsply Sirona CEREC Ortho Software (K171122)

Device Description:

iOrtho (hereafter referred to as "Proposed Device") includes modifications to the currently marketed software included in K203688, cleared October 8, 2021 (hereafter referred to as "Reference Device"). The Proposed Device is an orthodontic appliance design and treatment simulation software. This software is for use by dental professionals to aid in diagnosis and design solutions for patients. Digital scans (3D) of a patient's dentition can be loaded into the software and the dental professional can then create treatment plans for each individual patient and their needs. The system can be used to fabricate 3D dental models

using standard stereolithographic (STL) files for use in 3D printers. These models can then be used as a template for thermoforming aligners or retainers by Angel Align technicians.

Indications for Use:

iOrtho is intended for use as a medical front-end device providing tools for management of orthodontic cases, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Export of Models, Indirect Bonding Transfer Media, Sequential aligners) 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 iOrtho 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 to Predicate Devices:

The Proposed Device is functionally equivalent to the following device: 3Shape A/S Ortho System (K171634, cleared Jan 17, 2018) (hereafter referred to as "Predicate Device"), and possesses minor differences to the previously cleared Reference Device to allow treating physicians include mandible repositioning and traction accessories during treatment planning and simulation. The following table demonstrates the functional specifications of the Proposed Device are substantially equivalent to the Predicate Device, minorly different to the Reference Device, and raises no new questions regarding safety and effectiveness of the device.

Device Comparison Table

Specification	**Proposed Device:** iOrtho	**Predicate Device:** 3Shape A/S Ortho System (K171634)	**Reference Device:** Wuxi EA Medical Instruments Technologies Limited. Clear Aligner (K203688)	**Reference Device:** Dentsply Sirona CEREC Ortho Software (K171122)	**Comparison Result**
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	21 CFR 872.5470	21 CFR 872.5470	Same
Classification Name	Orthodontic Plastic Bracket (Software)	Orthodontic Plastic Bracket (Software)	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket (Software)	Same as Predicate
Product Code	PNN	PNN	NXC	PNN	Same
Classification	Class II	Class II	Class II	Class II	Same
Indication for Use	iOrtho is intended for use as a medical front-end device providing tools for management of orthodontic cases,	The 3Shape Ortho System™ is intended for use as a medical front-end device providing tools for management of orthodontic	Clear Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion in patients with	CEREC Ortho Software is intended for use with image data acquired from handheld intra oral 3D cameras and	Similar to predicate

Specification	**Proposed Device:** iOrtho	**Predicate Device:** 3Shape A/S Ortho System (K171634)	**Reference Device:** Wuxi EA Medical Instruments Technologies Limited. Clear Aligner (K203688)	**Reference Device:** Dentsply Sirona CEREC Ortho Software (K171122)	**Comparison Result**
	systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Export of Models, Indirect Bonding Transfer Media, Sequential aligners) 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 iOrtho requires the user to have the necessary training and domain knowledge in the practice of	models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Custom Metal Bands, 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 Ortho System™ requires the user to have the necessary training and domain knowledge in the	permanent dentition (i.e. all second molars).	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.	

Specification	**Proposed Device:** iOrtho	**Predicate Device:** 3Shape A/S Ortho System (K171634)	**Reference Device:** Wuxi EA Medical Instruments Technologies Limited. Clear Aligner (K203688)	**Reference Device:** Dentsply Sirona CEREC Ortho Software (K171122)	**Comparison Result**
	orthodontics, as well as to have received a dedicated training in the use of the software.	practice of orthodontics, as well as to have received a dedicated training in the use of the software.			
Technological Features	• Stand Alone Software • Imports Digital Dental Data • Useful for as an aid in Diagnosis, and treatment planning • Virtual Planning of tooth movement • Patient follow-up monitoring and management • Cephalometry	• Stand Alone Software • Imports Digital Patient Scans • Can be used to design Dental Casts • Useful for Diagnosis, treatment planning, and CAD design • Virtual Planning of tooth movement	• Produce 3D-model file of the PVS impression or digital scan. • Identifies the individual teeth that will require treatment (i.e. repositioning). • Creates a treatment plan (i.e. 3-D models that represent the treatment plan). The treating dental practitioner reviews these images using software and has the option to reject or request modifications	• Stand Alone Software • Imports Digital Patient Scans • Can be used to design Dental Models	Similar to Predicate

Specification	**Proposed Device:** iOrtho	**Predicate Device:** 3Shape A/S Ortho System (K171634)	**Reference Device:** Wuxi EA Medical Instruments Technologies Limited. Clear Aligner (K203688)	**Reference Device:** Dentsply Sirona CEREC Ortho Software (K171122)	**Comparison Result**
			to the set-up prior to approval.		
Minimum Hardware/Software Requirements	• **OS:** Windows 7)/Mac OS 10.12 • **RAM:** 2 GB • **Video Card:** Any that supports webGL • **Hard Drive Space:** 50MB • **Web browser (iOrtho):** Chrome 63+, Firefox 58+, Safari 12+, Edge 79+ • **Internet Access**	• **OS:** Windows 7, 8, 10 64-bit • **RAM:** 8 GB • **Video Card Memory:** 1 GB • **Hard Drive Space:** 250 GB • **CPU**: Intel Core i5 or equivalent • **Mouse:** with wheel button	• **OS:** Windows 7, 10, Mac OS X • **RAM:** 2 GB (minimum) • **Hard Drive Space:** 50 MB • **Video Card:** Graphics Display Card supporting webGL • **Web Browser:** Chrome 9+, Firefox 4+, Safari 5.1+, Edge 5.1+, IE11+ • **Internet Access**	• **OS:** Windows 7, 64-bit • **RAM:** 8 GB • **Video Card Memory:** 1 GB • **Hard Drive Space:** 250 GB • **CPU**: Intel QuadCore 1.6 GHz processor	Similar
Login Method	Username and password	Username and password	Username and password	Unknown	Same
Supported Anatomic Areas	Maxilla/Mandible	Maxilla/Mandible	Maxilla/Mandible	Maxilla/Mandible	Same
<u>Intended Use</u>					

Specification	Proposed Device: iOrtho	Predicate Device: 3Shape A/S Ortho System (K171634)	Reference Device: Wuxi EA Medical Instruments Technologies Limited. Clear Aligner (K203688)	Reference Device: Dentsply Sirona CEREC Ortho Software (K171122)	Comparison Result
Managing Patient and case base data	Yes	Yes	Yes	Yes	Same
Collection of study material	Yes	Yes	Yes	Yes	Same
Segmenting of study material (Segmenting gums/bone)	Yes – auto-segmented with manual adjustment	Yes – manual selection	Yes – manual selection	Yes – auto-segmented with manual adjustment	Similar
Alignment of study material	Yes	Yes	Yes	Yes	Same
Measuring study material	Yes	Yes	Yes	Yes	Same
Measurement point selection	Automatic with manual adjustment	Manual selection	Manual selection	Automatic with manual adjustment	Similar
Analyzing study material	Yes	Yes	Yes	Yes	Same
Treatment simulation	Yes	Yes	Yes	N/A	Same
Treatment Options	Up to unlimited number of stages	No limit on number of stages	Up to unlimited number of stages	N/A	Similar
Virtual appliance design	Yes	Yes	Yes	Yes	Same
Surface scan for intraoral scanner	Yes	Yes	Yes	Yes	Same
Surface scan from STL file	Yes	Yes	Yes	Yes	Same
	Analysis and Treatment				
Arch shape	Yes	Yes	Yes	Yes	Same

Specification	Proposed Device: iOrtho	Predicate Device: 3Shape A/S Ortho System (K171634)	Reference Device: Wuxi EA Medical Instruments Technologies Limited. Clear Aligner (K203688)	Reference Device: Dentsply Sirona CEREC Ortho Software (K171122)	Comparison Result
Overbite/overjet	Yes	Yes	No	Yes	Same as Predicate
Occlusal map	Yes	Yes	Yes	Yes	Same
3D treatment simulation	Yes	Yes	Yes	N/A	Same
Orthodontic Appliance Search	Yes	Yes	Yes	N/A	Same
Appliance virtual preparation	Yes	Yes	Yes	N/A	Same
Orthodontic appliance design	Yes	Yes	Yes	N/A	Same
Orthodontic appliance export	Yes	Yes	Yes	N/A	Same
Managing Patient and Case Base Data					
Creating, editing, and copying patient data	Yes	Yes	Yes	Yes	Same
Creating, editing, and copying case data	Yes	Yes	Yes	Yes	Same

Comparison of Indications for Use to the Predicate and Reference Devices:

Based on the above comparison, the indications of use of the Proposed Device is nearly identical to that of the Predicate Device and similar to the Reference Device.

Based on the similarity of indication for use, the Proposed Device can be considered substantially equivalent to the Predicate Device.

Comparison of Technological Characteristics to Predicate and Reference Devices:

Based on the above comparisons, the design, construction, and performance characteristics of the Proposed Device are similar to that of the Predicate Device, and similar to the Reference Devices. The differences identified are not substantially different in operation of the device. Thus, the Proposed Device can be considered substantially equivalent to the Predicate Device.

Summary of Performance Data and Substantial Equivalence:

Utilizing FDA Guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (issued May 11, 2015) the Proposed Device, iOrtho underwent appropriate integration, verification, and validation testing. The software passed the testing and performed per its intended use.

The software has been designed, integrated, verified, and validated in accordance with IEC 62304-Medical device software – software life cycle processes.

Conclusion:

Based on comparison of indications for use, technological features, performance testing, and software validation testing, the Proposed Device, iOrtho, is substantially equivalent to the legally marketed Predicate Device, 3Shape Ortho System (K171634).