May 16, 2024

Huh Soo Ji
RA Specialist
1F~3F, 4F(Part), 5F, 265, Daeji-Ro, Suji-gu
Yongin-si, Gyeonggi-do 16882
SOUTH KOREA

Re: K233625
Trade/Device Name: Raydent SW
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN, NOF
Dated: April 19, 2024
Received: April 19, 2024

Dear Huh Soo Ji:

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
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Respiratory, ENT and Dental Devices
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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)*
K233625

Device Name
RAYDENT SW

Indications for Use *(Describe)*
RAYDENT SW is a software designed to assist dental professionals in planning patient treatment and designing treatment devices. The software performs simulations based on patient images, allowing reference to treatment plans, and is used as a tool to design treatment devices based on 3D mesh data. Treatment devices include prosthetic devices (Veneer, Crown, Bridge, In/Onlay) and orthodontic devices (Clear Aligner).

To use RAYDENT SW, users must have the necessary education and domain knowledge in orthodontic or prosthodontic practice and receive 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 – K233625

1. 510(k) Summary

The summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

2. Date: May 13, 2024

3. Administrative Information

Applicant		Ray Co., Ltd.
Address		1F~3F, 4F(Part), 5F, 265, Daeji-ro, Suji-gu, Yongin-si, 16882, Korea
Manufacturer	Name	Ray Co., Ltd.
	Address	1F~3F, 4F(Part), 5F, 265, Daeji-ro, Suji-gu, Yongin-si, 16882, Korea
	Tel	+82-31-605-1000
	Fax	+82-2-6280-5534
Contact Person	Name	Sooji Huh
	Email	sooji.huh@raymedical.co.kr

4. Device Information

Trade/Proprietary Name	RAYDENT SW
Common Name	Orthodontic Software
Device	Orthodontic plastic bracket
Regulation Number	21 CFR 872.5470
Class	2
Product Code	PNN, NOF
Review Panel	Dental

5. Predicate device

Parameter	Predicate Device	Reference Device	Reference Device
Device Name	Ortho System™	CEREC Ortho Software	ChairsideCAD
Manufacturer	3Shape A/S	Dentsply Sirona	EXOCAD GMBH
510(K) Number	K180941 Traditional 510k	K171122 Traditional 510k	Exemption from Premarket Notification
Classification name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	System, Optical Impression, Computer Assisted Design And Manufacturing (Cad/Cam) Of Dental Restorations
Regulation number	872.5470	872.5470	872.3661
Primary product code	PNN(Orthodontic software)	PNN(Orthodontic software)	NOF

6. Device Description

RAYDENT is a software that provides tools to simulate treatment plans based on patient images generated by compatible scanners and design treatment devices based on appropriate three-dimensional images. It allows dental offices to acquire patient data in conjunction with software on compatible imaging equipment and utilize the acquired images to create treatment plans and devices for skilled dentists and oral and maxillofacial specialists.

7. Indication for use

RAYDENT SW is a software designed to assist dental professionals in planning patient treatment and designing treatment devices. The software performs simulations based on patient images, allowing reference to treatment plans, and is used as a tool to design treatment devices based on 3D mesh data. Treatment devices include prosthetic devices (Veneer, Crown, Bridge, In/Onlay) and orthodontic devices (Clear Aligner).

To use RAYDENT SW, users must have the necessary education and domain knowledge in orthodontic or prosthodontic practice and receive dedicated training in the use of the software.

8. Comparison with predicate device

The following table provides the summary of the technological characteristics of RAYDENT SW compared to the predicate device

Parameter	Proposed Device	Predicate Device	Reference Device	Reference Device
Manufacturer	RAY Co., Ltd.	3Shape A/S	Dentsply Sirona	EXOCAD GMBH
Device name	RAYDENT SW	Ortho System™	CEREC Ortho Software	ChairsideCAD
510(K) Number	(Traditional 510K)	K180941 (Traditional 510K)	K171122 (Traditional 510K)	Exemption from Premarket Notification
Common Name	Orthodontic Software	Orthodontic Software	Orthodontic Software	System, Optical Impression, Computer Assisted Design And Manufacturing (Cad/Cam) Of Dental Restorations
Classification Product Code	PNN, NOF	PNN	PNN	NOF
Indications for use	RAYDENT SW is a software designed to assist dental professionals in planning patient treatment and designing treatment devices. The software performs simulations based on patient images, allowing reference to treatment plans, and is used as a tool to design treatment devices based on 3D mesh data. Treatment devices include prosthetic devices (Veneer, Crown, Bridge, In/Onlay) and orthodontic devices (Clear Aligner). To use RAYDENT SW, users must have the necessary education and domain knowledge in orthodontic or prosthodontic practice and receive 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.	ChairsideCAD is a software device intended to support the design of dental restorations such as inlays, onlays, crowns, copings, veneers, bridges, pontics, provisionals and bite splints via a 3D CAD tool. The design is based on suitable 3D scans of the patient's dental anatomy produced by a compatible scanner. The software generates geometrical output of the design for manufacturing on compatible CAM systems. ChairsideCAD is intended to be used by trained professionals in dental practices and is not to be used for any purpose other than the design of dental restorations or bite splints, nor is it to be used for designing dental abutments.

Minimum Hardware/ Software Requirements	CPU : Intel Core i5 RAM : 16GB GPU : NVIDIA GeForce RTX 2060 6GB Storage : 1TB SSD Resolution : 1920 x 1080 LAN : 1Gbps Ethernet OS : Windows 10 x64 or Windows 11 x64	CPU : Intel Core i5 or equivalent RAM : 8GB GPU : 1GB Storage : 250GB Resolution : 1280 x 800 or similar LAN : Network Internet connection OS : Windows 7, 8 or 10 64-bit	CPU : Intel QuadCore 1.6 GHz processor RAM : 8GB GPU : NVidia or AMD graphics card 1 GB Storage : 250GB hard disk OS : Windows 7, 64-bit	CPU : Quad-Core RAM : 4GB GPU : 1GB Resolution : 1920 x 1080 OS : Windows 10 64 bit
Support Images	DICOM, 2D and 3D images (PLY, OBJ, STL)	DICOM, STL, JPG, BMP, PNG	Intra-oral scan data, STL	DICOM, 2D and 3D images(STL, OFF, OBJ, PLY)
Supported anatomic areas	Maxilla, Mandible	Maxilla, Mandible	Maxilla, Mandible	Maxilla, Mandible
Functionality	- Acquisition of oral topography image data - Creation of virtual 3D virtual dental models - Alignment of 3D virtual dental models - Measurement of 3D virtual dental models - Analysis of 3D virtual dental models - Orthodontic treatment simulation - Virtual orthodontic appliance design - Exporting of 3D virtual model, analysis and treatment case data - Prosthesis design	- Acquisition of oral topography image data - Creation of virtual 3D virtual dental models - Alignment of 3D virtual dental models - Measurement of 3D virtual dental models - Analysis of 3D virtual dental models - Orthodontic treatment simulation - Virtual orthodontic appliance design - Exporting of 3D virtual model, analysis and treatment case data	- Acquisition of oral topography image data - Creation of virtual 3D virtual dental models - Alignment of 3D virtual dental models - Measurement of 3D virtual dental models - Analysis of 3D virtual dental models - Exporting of 3D virtual model and analysis data	- Design of dental restorations - Geometrical output of the design for manufacturing on compatible CAM systems
Analysis Features	- Define occlusion - Tooth segmentation - Measure length and angle in the frontal and lateral direction - Define the tooth and set the tooth axis - Tooth width measurements - Bolton analysis - IPR	- Occlusal mapping - Tooth and gingiva separation/segmentation - Definition of dental arch shape and length - Tooth width measurements - Bolton’s analysis - Space analyses	- Occlusal mapping - Tooth and gingiva separation/segmentation - Definition of dental arch shape and length - Tooth width measurements - Bolton’s analysis - Nance and Moyer space analyses	N/A

Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices	YES	N/A	YES	N/A
Prosthesis design	Crown	N/A	N/A	Crown
	Pontic			Pontic
	Bridge			Bridge
	Veneer			Veneer
	Inlay/Onlay			Inlay/Onlay
	Temporary Denture			Provisional restorations
	eModel			Bite splints
	-			Coping
	-			Abutment

The product is principally just the same as in the previous 510(k) #K180941, #K171122 and the ChairsideCAD.
The complete of differences of the subject device to the predicate #K180941 and #K171122 devices are as follows
- Minimum Hardware/Software Requirement
- Support images
- Prosthesis design

The orthodontic treatment simulation and virtual orthodontic appliance design capabilities are the same of the #K180941.
Additionally, the prosthesis design capabilities are the same of the ChairsideCAD.

9. Performance Testing

Software, hardware, and integration verification and validation testing was performed in accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Device Software Functions" and “Guidance for the Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”.

The validation suite includes validation of implemented mitigations related to device hazards identified in the risk management procedures.

All test results have been reviewed and approved, showing the RAYDENT SW to be substantially equivalent to the predicate devices.

The documentation level of RAYDENT SW corresponds to basic documentation level based on the intended use, design, and risk of device software functionality.

10. Clinical Testing

Clinical testing is not a requirement and has not been performed.

11. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification. Ray Co., Ltd. concludes that the newly RAYDENT SW is substantially equivalent to the predicate device as described herein.