May 8, 2026

Hangzhou ChohoTech Co., Ltd.
% Ariel Xiang
Official Correspondent
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Bldg., 1500# Century Ave.
Shanghai,
CHINA

Re: K260419
Trade/Device Name: LingOral Dental Design System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN, NOF
Dated: February 9, 2026
Received: February 9, 2026

Dear Ariel Xiang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260419

Please provide the device trade name(s).

LingOral Dental Design System

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary - K260419

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:2025/11/21

3. Administrative Information

Applicant	Hangzhou ChohoTech Co., Ltd.
Address	Room 405, F4, Building 5, No. 188, LianChuang Street, Yuhang District, Hangzhou, Zhejiang, China
Contact Person	Cui Jianqiao
Email	cjianqiao@chohotech.com

4. Device Information

Trade/Proprietary Name	LingOral
Common Name	LingOral Dental Design System
Device	21 CFR 872.5470
Regulation Number	Orthodontic Plastic Bracket (Software)
Class	2
Product Code	PNN

5. Predicate device

Device Name:RAYDENT SW,
510(k) Number: K233625
RAY Co., Ltd.

6. Device Description

LingOral 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

LingOral 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 LingOral, 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. Product Comparison Table

Parameter	Proposed Device	Predicate Device	Remark
Manufacturer	Hangzhou ChohoTech Co., Ltd.	RAY Co., Ltd.	-
Device name	LingOral	RAYDENT SW	-
510(K) Number	/	K233625	-
Common Name	LingOral Dental Design System	Orthodontic Software	-
Classification Product Code	PNN	PNN, NOF	SE
Indications for use	LingOral 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 LingOral, users must have the necessary education and domain knowledge in orthodontic or prosthodontic practice and receive dedicated training in the use of the software.	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	SE

		education and domain knowledge in orthodontic or prosthodontic practice and receive dedicated training in the use of the software.	
Minimum Hardware/ Software Requirements	CPU: Multi‑ core x86‑ 64 processor (e.g., Intel® Core™ i7 or equivalent/higher) Memory: ≥ 16 GB RAM (32 GB recommended) Storage: ≥ 512 GB SSD for case data and temporary files GPU: Discrete GPU supporting CUDA (e.g., NVIDIA RTX series, ≥ 6 GB VRAM) Display: Resolution ≥ 1920×1080 with 3D rendering capability Network: Stable internet connection, latency ≤ 100 ms, IPv4/IPv6 supported Operating systems: Windows 10 or later; macOS 10.15 or later; Linux (mainstream distributions such as Ubuntu 20.04+ or later) 64‑ bit Google Chrome desktop application supported	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	Similar
Support Images	DICOM, 2D and 3D images (PLY, OBJ, STL)	DICOM, 2D and 3D images (PLY, OBJ, STL)	SE
Supported anatomic areas	Maxilla, Mandible	Maxilla, Mandible	SE

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	- 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	SE, Proposed Device Except for lacking the Prosthesis design functionality, all other features align with those of the Predicate Device.
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	- 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	SE
Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices	YES	YES	SE
Prosthesis design	NO	Crown Pontic Bridge Veneer Inlay/Onlay Temporary Denture eModel	Proposed Device have no Prosthesis design function,which have no impact on safety and efficacy.

The function of Proposed Device is less than Predicate Device， Minimum Hardware/ Software Requirements between Proposed Device and Predicate Device is a little different,Verification has confirmed that these minor variations do not affect the product's safety and efficacy.

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 LingOral Dental Design System to be substantially equivalent to the predicate devices.

The documentation level of LingOral Dental Design System 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. Hangzhou ChohoTech Co., Ltd. concludes that the LingOral Dental Design System is substantially equivalent to the predicate device as described herein.