February 23, 2022

Ewoosoft Co., Ltd.
% Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
IRVINE CA 92612

Re: K220003
Trade/Device Name: EzOrtho v1.3
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: December 27, 2021
Received: January 4, 2022

Dear Ms. Chung:

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K220003

Device Name
EzOrtho v1.3

Indications for Use *(Describe)*
EzOrtho is a software indicated for use by dentists who provide orthodontic treatment for image analysis, simulation, profilogram, VTO/STO and patient consultation. Results produced by the software's diagnostic, treatment planning and simulation tools are dependent on the interpretation of trained and licensed practitioners or dentists.

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

(K220003)

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

1. **Date:** Jan 20, 2022

2. **Applicant / Submitter**

Ewoosoft Co., Ltd.
801-ho, Vatechnetworks Bldg., 13, Samsung 1-ro 2-gil,
Hwaseong-si, Gyeonggido , Republic of Korea
Tel: +82 31 8015 6172 Fax: +82 31 8015 6196
Contact person: Young Seok Kim
Email: eddie.kim@ewoosoft.com

3. **U.S. Designated Agent**

Priscilla Chung
LK Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
Irvine, CA 92612
Tel: 714.202.5789 Fax: 714.409.3357
Email: juhee.c@LKconsultingGroup.com

4. **Trade/Proprietary Name:**

EzOrtho v1.3

5. **Common Name:**

Dental Imaging Software

6. **Classification:**

Medical Image Management and Processing System (21CFR 892.2050, Product code LLZ, Class 2, Radiology)

7. **Device Description:**

EzOrtho is a 2D orthodontic analysis and simulation program developed by Ewoosoft. It is of Moderate level of concern.
EzOrtho manages patient information and images for orthodontic analysis. This software also assists in orthodontic treatment by providing accurate image analysis, profilograms,

superimpositions, and VTO (visualised treatment objective) and STO (surgical treatment objective) simulations. The analyzed results are saved in chart format so that the user can easily store and track the treatment and records of each patient.

8. Indication for use:

EzOrtho is a software indicated for use by dentists who provide orthodontic treatment for image analysis, simulation, profilogram, VTO/STO and patient consultation. Results produced by the software's diagnostic, treatment planning and simulation tools are dependent on the interpretation of trained and licensed practitioners or dentists.

9. Predicate Device:

- Manufacturer: Ewoosoft Co., Ltd.
- Device: EzOrtho v1.2
- Classification: Medical Image Management and Processing System (21CFR 892.2050, Product code LLZ, Class 2, Radiology)
- 510(k) Number: K211793

10. Substantial Equivalence:

	Modified Device	Unmodified Device
Device name	EzOrtho v1.3	EzOrtho v1.2
510K number	K220003	K211793
Manufacturer	Ewoosoft	Ewoosoft
Indications for use	EzOrtho is a software indicated for use by dentists who provide orthodontic treatment for image analysis, simulation, profilogram, VTO/STO and patient consultation. Results produced by the software's diagnostic, treatment planning and simulation tools are dependent on the interpretation of trained and licensed practitioners or dentists.	EzOrtho is a software indicated for use by dentists who provide orthodontic treatment for image analysis, simulation, profilogram, VTO/STO and patient consultation. Results produced by the software's diagnostic, treatment planning and simulation tools are dependent on the interpretation of trained and licensed practitioners or dentists.
Platform	IBM-compatible PC or PC network	IBM-compatible PC or PC network
Operating System	Microsoft Window 10	Microsoft Window 10
User Interface	Mouse, Keyboard	Mouse, Keyboard
Image Input Sources	Images can be scanned, loaded from digital cameras or card readers, or imported from a radiographic imaging device	Images can be scanned, loaded from digital cameras or card readers, or imported from a radiographic imaging device
32 bit / 62 bit	32 bit / 62 bit	32 bit / 62 bit
Image format	DICOM, BMP, JPG, PNG, TIF	DICOM, BMP, JPG, PNG, TIF
Patient Database Compatibility	SQL	SQL
Includes Image Measurement tools	Linear distance, angle	Linear distance, angle
Image viewing	Full, side by side, thumbnail	Full, side by side, thumbnail
Image manipulation	Grayscale, invert, emboss, brightness, contrast, gamma, sharpen, median, despeckle, hue, saturation, equalize flip, mirror, masking, rotate, annotation, cephalometric tracing, implant simulations	Grayscale, invert, emboss, brightness, contrast, gamma, sharpen, median, despeckle, hue, saturation, equalize flip, mirror, masking, rotate, annotation, cephalometric tracing, implant simulations
Cephalometric tracing	In addition to the user-configured analysis, standard orthodontic tracing analysis include: Downs Jarabek McNamara Ricketts Jefferson	In addition to the user-configured analysis, standard orthodontic tracing analysis include: Downs Jarabek McNamara Ricketts Jefferson
Implant module	Generic	Generic
3D imaging capability	None.	None.
Image annotation	Text, paint, ellipse, pointer, select, draw, magnify, line, rectangle, ruler, protractor, brush, select region, copy / paste	Text, paint, ellipse, pointer, select, draw, magnify, line, rectangle, ruler, protractor, brush, select region, copy / paste

EzOrtho v1.3 described in this 510(k) has the same intended use and the same technical characteristics as the unmodified device.

The subject device and the unmodified device are substantially equivalent, having the same indications for use and functionalities like operation software, computer platform, picture archiving and communication format, image format, image processing features, windowing, image edit, measurements and manipulation.

The modifications are changes in PC system requirement information, upgrading the SETTINGS tab (font size change option for analysis chart), upgrading the PATIENT Tab (reset to original DICOM pixel spacing), upgrading the VIEWER Tab (change layouts in presentation mode), upgrading the ANALYSIS Tab (exporting analysis chart), upgrading the PRACTICE Tab (UI upgrade and recurrence option).These differences are not significant since they are additional features for user convenience and do not raise the questions of safety or effectiveness. Based on the test results submitted in this 510K, we conclude that the subject device is substantially equivalent to the predicate device.

11. Technological Characteristics:

EzOrtho is a software device that does not contact the patient, nor does it control any life sustaining devices. Results produced by the software's diagnostic, treatment planning and simulation tools are dependent on the interpretation of trained and licensed radiologists, clinicians and referring physicians as an adjunctive to standard radiology practices for diagnosis.

12. Performance Data:

SW verification/validation and the measurement accuracy test were conducted to establish the performance, functionality and reliability characteristics of the modified devices. The device passed all of the tests based on pre-determined Pass/Fail criteria.

13. Conclusion:

The subject device is substantially equivalent in the areas of technical characteristics, general function, application, and indications for use. The new device does not introduce a fundamentally new scientific technology, and the device has been validated through system level test. Therefore, we conclude that the subject device described in this submission is substantially equivalent to the predicate device.