Ewoo Soft Co., Ltd.                                                                              October 22, 2020
℅ Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt STE 200
IRVINE CA  92620

Re:  K202948
     Trade/Device Name:  EzOrtho
     Regulation Number:  21 CFR 892.2050
     Regulation Name:  Picture archiving and communications system
     Regulatory Class:  Class II
     Product Code:  LLZ
     Dated:  September 22, 2020
     Received:  September 30, 2020

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,

For

Thalia T. Mills, Ph.D.
Director
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

## Indications for Use

510(k) Number *(if known)*

K202948

Device Name

EzOrtho

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.

# 510(k) Summary
(K202948)

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

1. **Date:** 10/12/2020

2. **Applicant / Submitter**

   Ewoosoft Co., Ltd.
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   Hwaseong-si, Gyeonggido , Republic of Korea
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   Contact person: Young Seok Kim
   Email: eddie.kim@ewoosoft.com

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

   Priscilla Chung
   LK Consulting Group USA, Inc.
   1150 Roosevelt STE 200
   Irvine, CA 92620
   Tel: 714.202.5789        Fax: 714.409.3357
   Email: juhee.c@LKconsultingGroup.com

4. **Trade/Proprietary Name:**

   EzOrtho

5. **Common Name:**

   Dental Imaging Software

6. **Classification:**

   - Device: System, image processing, radiological
   - Regulation Name: Picture Archiving and Communication Systems
   - Review Panel: Radiology
   - Device Class: Class 2
   - Product Code: LLZ,
   - Regulation Number: 21CFR 892.2050

## 7. Device Description:

EzOrtho is a 2D orthodontic analysis and simulation program developed by Ewoosoft. 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.

EzOrtho is designed to provide a simple and straightforward user interface.

- Managing Patients and Registering Images
  EzOrtho offers features for making schedules and managing patient appointments. In addition, EzOrtho enables the users to import images from EzDent-i made by our company, Explorer, or a scanner, and easily calibrate the size of the image or arrange multiple film/photo images.

- Analyzing and Tracing Images
  The Landmark Voice Guide and the improved Landmark Input Interface features support easier tracing.

- Establishing Treatment Plans
  The Morphing feature enables the user to predict how the treatment plan established may affect the face of a patient. In addition, the Compare feature enables the user to establish a treatment plan by comparing photos before and after the treatment.

- Assisting with Patient Consultation
  EzOrtho provides features to facilitate understanding and communication between doctors and patients during consultation. For example, the Superimposition feature displays after surgery changes visually, and the Gallery feature plays a slide show with multiple images of patients.

## 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:

EzOrtho (K192888) by Ewoosoft Co., Ltd.

- Device: System, image processing, radiological
- Regulation Name: Picture Archiving and Communication Systems

- Review Panel: Radiology
- Device Class: Class 2
- Product Code: LLZ,
- Regulation Number: 21CFR 892.2050

## 10. Substantial Equivalence:

EzOrtho v1.1 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 adding Help Document, upgrading the Patient Tab(quick search(recently added), exporting patient information, export to 3rd party SW, hide the displayed patient information), upgrading the Viewer Tab(adding reference line, adding image information), upgrading the Analysis Tab(Print Chart) and upgrading the Consult Tab(removing from favorites).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:

Verification, validation and testing activities 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 new device and predicate device are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. The new device does not introduce a fundamentally new scientific technology, and the modifications are validated through system level test. Therefore, it is our opinion that the EzOrtho described in this submission is substantially equivalent to the predicate device.