EWOO SOFT Co., Ltd.   March 13, 2020
℅ Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt STE 200
IRVINE CA 92620

Re: K192888
     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: February 5, 2020
     Received: February 11, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2020

See PRA Statement below.

510(k) Number *(if known)*
K192888

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

(K192888)

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

1. **Date:** 2/5/2020

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.
    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:**

    System, image processing, radiological (21CFR 892.2050, Product code LLZ, Class 2, Radiology)

7. **Device Description:**

    EzOrtho is a 2D orthodontic analysis 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). The analyzed results are saved in chart format so that you 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 powerful features related to making schedules and managing patient appointments. In addition, EzOrtho enables you to import images from EzDent-i(K190087, K172364, K163533, K161117, K150747), 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 support more accurate and easier tracing.

- Establishing Treatment Plans
  The Morphing feature enables you to predict how the treatment plan established may affect the face of a patient. In addition, the Compare feature enables you 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 the changes visually due to the treatment 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:

- Manufacturer: Ewoosoft Co., Ltd.
- Device: OrthoVision
- 510(k) Number: K173094

10. Substantial Equivalence:

Device name	EzOrtho v1.0	OrthoVision v2.1
510K number	K192888	K173094
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.	OtrhoVision software is indicated for use by orthodontists for image analysis, simulation, profilogram, growth forecast, 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 7, 8, 10	Microsoft Window 7, Window 8
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, gallery, 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, ceph growth projections, 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, polygon, ruler, protractor, smile library, smudge, brush, redeye reduction, select region, copy / paste

The EzOrtho v1.0 described in this 510(k) has the same indications for use and the same technical characteristics as the OrthoVision v2.1(K173094).

The EzOrtho v1.0 are substantially equivalent to the predicate device, 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 difference between the subject device and the predicate device is the UI/UX design, and also some of the additional functions have been removed from the subject device such as gallery, ceph growth projections, and some of the annotation features. It has been found that these functions and features are not really used by users so we decided to remove them to improve usability for ease of use. We believe this difference does not raise a question in substantial equivalence, because these features are merely additional and does not affect the device to achieve the intended use. The other difference is that an automatic cephalometric tracing feature is added to the subject device. With this function, the SW automatically input the cephalometric landmarks for user convenience. The users can still adjust the points manually when necessary. We performed the validation test to evaluate the accuracy of this auto feature.

Based on the results of software validation and performance tests, 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 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.