EWOO SOFT Co., Ltd.
% Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
690 Roosevelt
IRVINE CA 92620

October 26, 2017

Re: K173094
Trade/Device Name: OrthoVision
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 26, 2017
Received: September 29, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K173094

Device Name
OrthoVision

Indications for Use *(Describe)*

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.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

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

1. **Date:** 09/26/2017

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.
690 Roosevelt
Irvine, CA 92620
Tel: 714.202.5789 Fax: 714.409.3357
Email: juhee.c@LKconsultingGroup.com

4. **Trade/Proprietary Name:**

OrthoVision

5. **Common Name:**

Dental Imaging Software

6. **Classification:**

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

7. **Device Description:**

OrthoVision is a 2D orthodontic analysis and simulation program created by EWOOSOFT. OrthoVision manages patient information and images during orthodontic analysis. This software also assists in orthodontic treatment by providing accurate image analysis, growth forecasts, profilograms, superimpositions, and VTO/STO simulations. The analyzed results

are saved in chart format so that you can easily store and track treatment and records of each patient.

**8. Indication for use:**

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.

**9. Predicate Device:**

- Manufacturer: EWOOSOFT Co., Ltd.
- Device: OrthoVision
- 510(k) Number: K131570

**10. Substantial Equivalence:**

OrthoVision v2.1 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 differences are that the subject device has additional 2D Imaging Viewer link option, features in printing the current Appointment screen and searching for a patient in Appointment tab, Image Aligner feature for image box, and adding [Fusion to Original Image] function and Jefferson Analysis (T-Point). 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:**

OrthoVision 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 OrthoVision described in this submission is substantially equivalent to the predicate device.