August 17, 2022

AssembleCircle Corp.
% Edward Park
CEO
LightenBridge LLC
4408 Tortuga Ln
MCKINNEY TX 75070

Re: K220903
Trade/Device Name: WebCeph
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: August 9, 2022
Received: August 9, 2022

Dear Edward Park:

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
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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)*
K220903

Device Name
WebCeph

Indications for Use *(Describe)*
WebCeph is a software indicated for use by dentists who provide orthodontic treatment for image analysis, simulation, profilogram, VTO/STO (Visual Treatment Objective) 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. The device is only for the use of patients above 7 years old.

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.

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510(k) Summary – Traditional 510(k)

K220903

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information

Submitter Name:	AssembleCircle Corp.
Address:	R02-ho, 8th floor, 12, Daewangpangyo-ro 645beon-gil, Bundang-gu, Seongnam-si, Gyeonggi-do 13487 Republic of Korea
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Contact Person:	Edward Park, official correspondent of AssembleCircle Corp.
Date of submission:	Mar 23, 2022

Device Information

Proprietary Name(s):	WebCeph
Common Name:	Medical Imaging Software
Classification Name:	Medical image management and processing system per 21 CFR 892.2050
Product Code:	LLZ
Classification Panel:	Radiology
Device Class:	II

Device Description

WebCeph is a 2D orthodontic analysis program. It manages patient information and images for orthodontic analysis. This software also assists in orthodontic treatment by providing accurate image analysis, profilograms, superimpositions, and VTO (visualized treatment objective) and STO (surgical treatment objective). The analyzed results are saved in chart format so that the users can easily store and track the treatment and records of each patient. This device is designed to provide a simple and straightforward user interface.

WebCeph is used for registering orthodontic medical images and managing the patient information through the features of making schedules and managing patient appointments. This software receives image files (JPG, BMP, PNG) as input source and enables the users to easily calibrate the size of the image or arrange multiple film/photo images.

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The feature of anatomical landmark detection support more accurate and easier tracing by enabling the user precisely to adjust the position of the detected landmarks.

After image alignment, orthodontic treatment simulation and Maxillo-facial surgical planning simulation can be performed. The Morphing feature enables the dentist user to predict how the treatment plan established may affect the face of a patient. In addition, the Compare feature enables the dentist user to establish a treatment plan by comparing photos before and after the treatment.

Cephalometric analysis results are provided as a report. The report can be saved in PDF file or Excel file format. For the evaluation of treatment progress, the software automatically superimposes the lateral cephalographic image.

This software 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.

Predicate Device

- EzOrtho (Ewoosoft Co., Ltd. K192888, 03/13/2020)
  CFR 892.2050, Medical image management and processing system (Product Code: LLZ)

Indications for Use

WebCeph is a software indicated for use by dentists who provide orthodontic treatment for image analysis, simulation, profilogram, VTO/STO (Visual Treatment Objective) 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. The device is only for the use of patients above 7 years old.

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Device Comparison Table on Features and Functions

Device Name	WebCeph	EzOrtho
510k number		**K192888**
Manufacturer	AssembleCircle Corp.	Ewoosoft Co., Ltd.
Indications for Use	WebCeph is a software indicated for use by dentists who provide orthodontic treatment for image analysis, simulation, profilogram, VTO/STO (Visual Treatment Objective) 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. The device is only for the use of patients above 7 years old.	EzOrtho is a software indicated for use by dentists who provide orthodontic treatment for image analysis, simulation, profilogram, VTO/STO (Skull Growth and Visual Treatment Objective) 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, 8, 10
User Interface	Mouse, Keyboard	Mouse, Keyboard
CPU processor type	x64-based processor or higher	x32 / x64 - based processor
Image Communication Standard	BMP, JPG, PNG	DICOM BMP, JPG, PNG, TIF
Modality Support	X-ray, or CT	X-ray, or CT
Component	Client (Internet Browser)	Client or Standalone software
Database Compatibility	PostgreSQL	MS SQL
Image Measurement tools	Linear distance, angle	Linear distance, angle
Image viewing	Full, side by side, thumbnail, Zoom in / out, template	Full, side by side, thumbnail, Zoom in / out
Image manipulation	Brightness, contrast, flip, rotate, annotation, cephalometric tracing	Brightness, contrast, equalize flip, rotate, annotation, cephalometric tracing, grayscale, invert, emboss,

Device Name	WebCeph	EzOrtho
510k number		**K192888**
Manufacturer	AssembleCircle Corp.	Ewoosoft Co., Ltd.
		gamma, sharpen, median, despeckle, hue, saturation, mirror, masking, implant simulations
Cephalometric tracing	In addition to the user-configured analysis, standard orthodontic tracing analysis include: Downs, Steiner, Jarabek, McNamara, Ricketts, Eastman, Kim, Wits	In addition to the user-configured analysis, standard orthodontic tracing analysis include: Downs, Jarabek, McNamara, Ricketts, Jefferson
Implant module	None	Generic
3D imaging capability	None	None
Image annotation	Paint, draw, magnify, line drawing, distance measure (px or mm), 3-point angle, ruler(calibrate), select region crop	Text, paint, draw, magnify, line drawing, distance measure (px or mm), ruler, select region, ellipse, pointer, rectangle, protractor, brush, copy / paste
Treatment Planning, Simulation and follow up	- Translate, tip and rotate incisors, reposition molars, rotate mandible - Superimpose one or more growth tracings over original tracing - Treatment result prediction simulation on a traced x-ray or tracing overlaid on photograph VTO – Visual Treatment Objective STO – Surgical Treatment Objective (Orthognathic surgery) Warping and Morphing	- Translate, tip and rotate incisors, reposition molars, rotate mandible - Superimpose one or more growth tracings over original tracing - Growth Forecast - Growth simulation on a traced x-ray or tracing overlaid on photograph VTO – Visual Treatment Objective STO – Surgical Treatment Objective (Orthognathic surgery) Warping and Morphing
Supported Area	Dental, Maxilla, Mandible	Dental, Maxilla, Mandible

All the indications for use of the subject device are within those of the predicate device. The only difference in Indications for Use is that the EzOrtho (K192888) includes skull growth, but

WebCeph does not. Therefore, the subject device does not have such functions, but the following growth forecast, simulation, or tracing features are available only on the predicate device as treatment planning, simulation, and follow up. For cephalometric tracing, additional standard analysis methods - Steiner, Eastman, Kim, and Wits- are available on the subject device. All the other technical characteristics are identical or similar to each other, because all the other technical characteristics of WebCeph are within the range of the EzOrtho's.

Based on the results of software validation and performance tests, we conclude that the subject device is as safe and effective as the predicate device, and all the features and functions of subject device are substantially equivalent to the predicate device.

Technological Characteristics

WebCeph 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 dentists.

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.

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.