K131570

510(k) Summary

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

Date

May 28, 2013

Manufacturer

Ewoo Soft Co., Ltd
S-402, 231 Pangyoyeok-ro, Bundang-Gu,
Seongnam-Si, Gyeonggi-do, Korea, 463-400
Tel: +82 31 8015 6171
Fax: +82 31 6966 7420

Contact person: Mr. Young. Seok. Kim
Email: ys.kim@ewoosoft.com

AUG 15 2013

United States Sales Representative (U.S. Designated agent)

Mtech Group
12946 Kimberley Ln
Houston, TX 770779
Tel: +713-467-2607
Fax: +713-464-8880
Contact person: Mr. Dave Kim

Trade/Proprietary Name:

OrthoVision

Common Name:

Radiological Image Processing System

Classification Name:

System, image processing, radiological (21CFR 892.2050, Product code LLZ, Class2)

Description:

OrthoVision is a 2D orthodontic analysis and simulation program created by EWOO Software.

OrthoVision manages patient information and images during orthodontic analysis. This software also assists in orthodontic treatment by providing diagnostic image analysis, growth forecasts, profilograms, superimpositions, and VTO/STO simulations. The analyzed results are saved in a chart format and the user can easily store and track treatment records of each patient.

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.

Predicate Device:

Manufacturer	: Carestream Dental LLC.
Device	: CS Orthodontic and OMS
510(k) Number	: K122427 (Decision Date – September 12, 2012)

Comparison Table:

Characteristic	OrthoVision	CS Orthodontic and OMS Imaging v 11.0
510K number	K131570	K1222427
Manufacturer	EWOOSOFT	Carestream Dental LLC
Indications 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.	CS Orthodontic Imging and CS OMS Imaging Software is indicated for use by orthodontists or oral maxillofacial surgeons and their staff in storing and organizing images, including digital photographs and x-rays. The device includes the capability to trace digital cephalometric radiograph, analyze the measurements taken and make growth projections or surgical predicitons.
Platform	IBM-compatible PC or PC	IBM-compatible PC or PC

	network	network
Operating System	Microsoft Window 7, Window 8	Microsoft Windows
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 / 64 bit	32 bit / 64 bit	32 bit
Image format	BMP, JPG/JPEG, GIF	DICOM
Patient Database Compatibility	SQL	SQL
Includes Image Measurement tools	Linear distance, angle	Linear distance, angle
Image viewing	Full, side by side, gallery, 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, ceph growth projections,	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: Burstone Downs Jarabek McNamara Ricketts Steiner	In addition to the user-configured analysis, standard orthodontic tracing analysis include: Downs Jarabek McNamara Ricketts Roth Sassouni Steiner Twee,
Growth projections	Simulated growth projections on lateral photos used for patient communication	Simulated growth projections on lateral photos used for patient communication
Implant module	None	Include implant libraries from Nobel Biocare, Bicon, 3i, and Straumann, and generic
3D imaging capability	None.	None. Includes interface to 3D imaging software provided with Kodak 9000, Kodak 9500, or CS 9300 systems. CS Orthodontic and OMS imaging software does not view,

		transfer or process 3D radiographs.
Image annotation	Text, paint, ellipse, pointer, select, draw, magnify, line, rectangle, polygon, ruler, protractor, smile library, smudge, brush, redeye reduction, 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

Substantial Equivalence:

OrthoVision described in this 510(k) has the similar intended use and similar technical characteristics as CS Orthodontic and OMS of Carestream Dental LLC.

The model CS Orthodontic and OMS is the primary predicate device. The subject device and predicate device are substantially equivalent, having the similar indications for use and functionalities like operation software, image processing features, windowing, zoom, rotation. The differences are cosmetic, arrangement and components use only. Both OrthoVision, the proposed device, and CS Orthodontic and OMS, the predicate device are categorized in product code LLZ; equivalence between these models is evident.

Differences between the subject device and predicate device include the PC server requirements such as processor, RAM, networking and image format type. These differences do not raise any new questions of safety or effectiveness.

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. A physician, providing ample opportunity for competent human intervention interprets images and information being presented.

Nonclinical Testing:

The complete system configuration has been assessed and tested by the manufacturer and passed all in-house testing criteria. The software validation test was designed to evaluate all input functions, output functions, and actions performed by OrthoVision. Each operational mode and

the process followed are documented in the Software Validation Report.

The validation testing verified and validated the risk analysis and individual performance results were within the predetermined acceptance criteria.

Safety and Performance Data:

- IEC 62304 Medical device software – Software life-cycle processes : 2006
- ISO 14971 Medical Devices – Application of risk management to medical device : 2007

Conclusion:

The premarket notification for OrthoVision contains adequate information and data to determine substantial equivalence to the predicate device. 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 nonclinical tests demonstrate that the device is safe and effective. Therefore, it is our opinion that the OrthoVision described in this submission is substantially equivalent to the predicate device.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 15, 2013

EWOO SOFT CO., LTD
% DAVE KIM
MTECH GROUP
12946 KIMBERLEY LN
HOUSTON TX 77079

Re: K131570
Trade/Device Name: OrthoVision
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 09, 2013
Received: August 06, 2013

Dear Mr. Kim:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131570

Device Name: OrthoVision

Indications 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.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

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