March 21, 2018

HDX WILL CORP.
℅ Myoung-Joon Lee
General Manager
#105, 106, 201, 202, 203, 204, 38, Osongsaengmyeong 4-ro,
Osong-eup, Heungdeok-gu
Cheongju-si, Chungcheongbuk-do 28161
KOREAN

Re: K172168
Trade/Device Name: WillCeph
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 22, 2018
Received: January 30, 2018

Dear Myoung-Joon Lee:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172168

Device Name
WillCeph

Indications for Use *(Describe)*
WillCeph is intended for use by specialized dental practices for capturing, storing and presenting patient images and radiographs and to aid in cephalometric analysis, orthodontic and orthognathic treatment planning and case follow-up. Results produced by the software tools are to be interpreted by trained and licensed dental practitioners.

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

[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

July 12, 2017

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Sponsor: HDX WILL CORP.
  - Address: #105, 106, 201, 202, 203, 204, 38, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Korea
- Contact Name: Myoung-Joon Lee / General Manager
  - Telephone No.: +82-43-710-7318
  - Fax No.: +82-43-710-7312
  - Email Address: mjlee@iwillmed.com
- Name of Manufacturer: Same as sponsor
  - Address: Same as sponsor

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

- Trade Name: WillCeph
- Common Name: PACS Software
- Classification:

Classification Name	System, Image Processing, Radiological
Classification Regulation	21 CFR 892.2050
Product Code	LLZ
Device Class	II
Classification Panel	Radiology

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow:

Predicate Device

- 510(k) Number: K131348
- Applicant: INFOMED SERVICIOS INFORMATICOS
- Classification Name: Imaging Processing System
- Trade Name: ORTOMED

5. Description of the Device [21 CFR 807.92(a)(4)]

■ **Overview**

- Description

• Cephalometric Analysis & Maxillo-facial Surgical Simulation

• Consulting, Diagnosis, Surgical Planning, Analysis, Growth Forecast

- Specification

• Patient data management : Patient Database

• Various Gallery format & User-defined gallery

• Image Fusion & Comparing : Pre / Post Treatment

• Cephalogram & Tracing on digitized X-ray film

• Treatment Simulation (VTO / STO)

• Chart & Analysis / Export into excel file

• Superimposition

• Photo-Film Image Fusion

• Growth Forecast

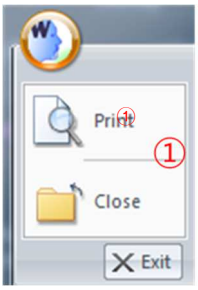
• PACS Integration (Option)

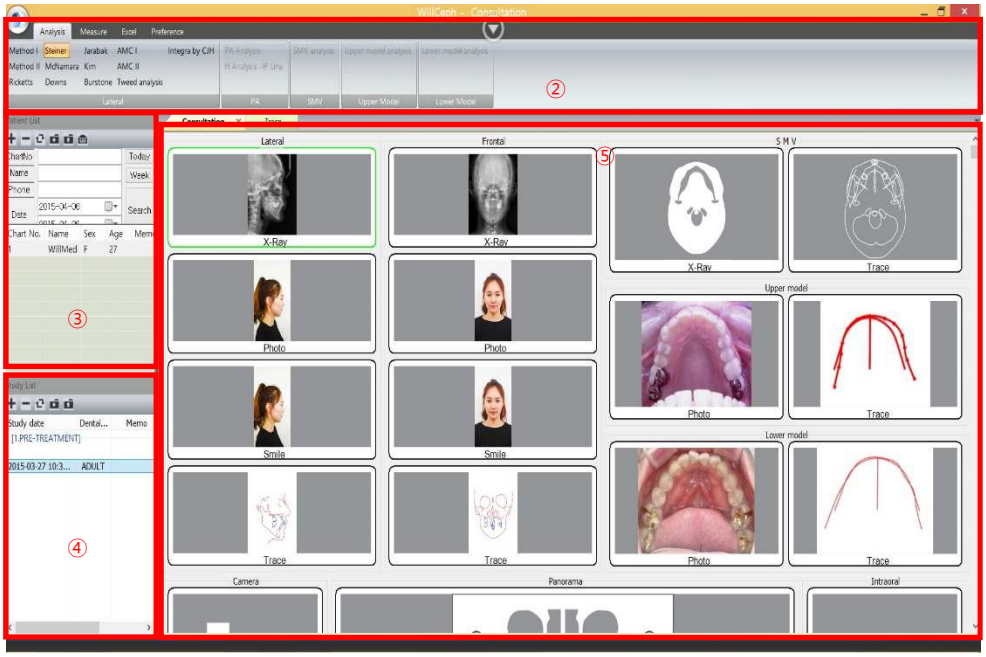
■ **System Requirements**

- Client or Standalone
  - OS : Microsoft Windows 7 or higher
  - CPU : Intel Core2Duo or higher
  - Memory : DDR2 2GB or higher
  - Storage Installation : 100MB free-space

    Data storage: depends on size of a data
  - Monitor : 1024 x 768 or higher
  - Input device : General keyboard & wheel mouse
- Hardware Lock key
  - OS : Microsoft Windows 7 or higher
  - Connection method : USB 2.0

■ **Program configuration**





① Menu: To print the currently selected screen, or you can exit the program.

② Top toolbar: Diagnostic items, measurements, and environment setting is available

③ Patient editing window:

I) Provides functions such as register new patient, modify, and delete.

II) Selected patient's information, information of the Study, and the image files can be exported as one output file.

III) Copy the image data in connection with the Will-Master.

④ Study editing window: Provides functions such as Study registration, modification, deletion and importing/exporting of images.

⑤ Output window:

Output the images of the selected Study in the Consultation screen, and provides functions such as Trace, VTO/STO, Growth Forecast, Super Impose, Chart, Gallery, etc.

6. Intended Use/Indications for Use [21 CFR 807.92(a)(5)]

WillCeph is intended for use by specialized dental practices for capturing, storing and presenting patient images and radiographs and to aid in cephalometric analysis, orthodontic and orthognathic treatment planning and case follow-up. Results produced by the software tools are to be interpreted by trained and licensed dental practitioners.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

There are no significant differences in the technological characteristics of this device compared to the predicate device which adversely affect safety or effectiveness. Provided below is a table summarizing and comparing the technological characteristics of the WillCeph and the predicate device:

	Proposed Device	**Predicate Device**
K Number	Not known	K131348
Model Name	WillCeph	ORTOMED
Manufacturer	HDX WILL CORP.	INFOMED SERVICIOS INFORMATICOS
Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological
Regulatory Number	21 CFR 892.2050	21 CFR 892.2050
Product Code	LLZ	LLZ
Classification	II	II
Intended Use	WillCeph is intended for use by specialized dental practices for capturing, storing and presenting patient images and radiographs and to aid in cephalometric analysis, orthodontic and orthognathic treatment planning and case follow-up. Results produced by the software tools are to be interpreted by trained and licensed dental practitioners.	ORTOMED is intended for use by specialized dental practices for capturing, storing and presenting patient images and radiographs and to aid in cephalometric analysis, orthodontic and orthognathic treatment planning and case follow-up. Results produced by the software tools are to be interpreted by trained and licensed dental practitioners.
Type of Use	Prescription Use	Prescription Use
Modality Support	X-ray	X-ray
Component	Client or Standalone software	Client or Standalone software
Operating System	Windows 7 or higher	Windows 2000/XP, Vista and Windows 7
User Interface	Mouse, Keyboard	Mouse, Keyboard
Image Communication Standard	DICOM	DICOM
Patient Data Management	Patient module for patient registration and file management. Image module for image management.	GESDEN module for patient registration and file management. GESIMAG module for image management.
Patient Database Engine	My SQL / Microsoft® SQL©	Microsoft® SQL©

	Proposed Device	**Predicate Device**
Image Measurement	Yes (linear, distance, angle)	Yes (linear, distance, angle)
Matching / Adjustment of Photograph to X-ray	Yes	Yes
Cephalometric Analyses	In addition to user-configured analysis, standard orthodontic tracing analyses include: - Lateral Analyses - Frontal Analyses - Models Analyses - Photo studies of soft tissues	In addition to user-configured analysis, standard orthodontic tracing analyses include: - Lateral Analyses - Frontal Analyses - Models Discrepancy Studies - Photo studies of soft tissue
Treatment Planning, Simulation and Follow-up	Orthodontic treatment - Translate, tip and rotate incisors, reposition molars, rotate mandible - Growth Forecast - Growth simulation on a traced x-ray or tracing overlaid on photograph - Superimpose one or more growth tracings over original tracing VTO – Visual Treatment Objective STO – Surgical Treatment Objective (orthognathic surgery) Warping and Morphing	Orthodontic treatment - Translate, tip and rotate incisors, reposition molars, auto-rotate mandible - Arch length discrepancy worksheet - CO/CR Conversion Growth Forecast (Ricketts algorithm) - Growth simulation on a traced x-ray or tracing overlaid on photograph - Superimpose one or more growth tracings over original tracing VTO – Visual Treatment Objective SVTO – Surgical Visual Treatment Objective (orthognathic surgery) Warping and Morphing

Non-Clinical Test Summary

WillCeph contains MODERATE level of concern software. Software was designed and developed according to a software development process and was verified and validated.

Software information is provided in accordance with FDA guidance: the content of premarket submissions for software contained in medical devices, issued on May 11, 2005.

Clinical Test Summary:

No clinical studies were considered necessary and performed.

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

WillCeph has the similar technical characteristics with the predicate devices. These devices are intended for use by specialized dental practices for capturing, storing and presenting patient images and radiographs and to aid in cephalometric analysis, orthodontic and orthognathic treatment planning and case follow-up. Results produced by the software tools are to be interpreted by trained and licensed dental practitioners.

The subject and primary predicate device share the same intended use, type of use, modality support and image communication standard. They also share equivalent operating systems. Therefore, WillCeph is substantially equivalent to legally marketed predicate device with respect to indications for use and technology characteristics.

9. Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification HDX WILL CORP., concludes that the WillCeph is substantially equivalent in safety and effectiveness to the predicate devices as described herein.