DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 8, 2017

HDX WILL CORP.
Seung-Il Chun
General Manager
#105, 201, 202, 203, 204, 38,
Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do, 28161
REPUBLIC OF KOREA

Re: K170180
Trade/Device Name: Will3D
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: March 7, 2017
Received: March 14, 2017

Dear Seung-Il Chun:

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 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 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,

For

Robert A. 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)*
K170180

Device Name
Will3D

Indications for Use *(Describe)*
Will3D is a software application used for the display and 3D visualization of medical image files from scanning devices, such as Dental CT scanner. It is intended for use by radiologists, clinicians, referring physicians and other qualified individuals to retrieve, process, render, review, store, print, assist in diagnosis, and distribute images utilizing standard PC hardware. Additionally, Will3D is a preoperative software application used for the simulation and evaluation of dental implants, orthodontic planning and surgical treatments.

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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#105, 201, 202, 203, 204, 38, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si,
Chungcheongbuk-do, 28161, Korea, Tel: +82-43-710-7318/ Fax: +82-43-710-7312

510(k) Summary

[As required by 21 CFR 807.92]

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

May 8, 2017

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

- Name of Sponsor: HDX WILL CORP.
  - Address: #105, 201, 202, 203, 204, 38, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Korea
- Contact Name: Seung-Il Chun / General Manager
  - Telephone No.: +82-43-710-7318
  - Fax No.: +82-43-710-7312
  - Email Address: sichun@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: Will3D
- 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:

Primary Predicate

- 510(k) Number: K070803
- Applicant: Anatomage Inc.
- Classification Name: Imaging Processing System
- Trade Name: InVivoDental™

Reference Predicate

- 510(k) Number: K113543
- Applicant: CyberMed Inc.
- Classification Name: Imaging Processing System
- Trade Name: OnDemand3D^{G2}

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

The Will3D is one of the components of a PACS (Picture Archiving and Communications System). The Will3D is the software application that provides image viewing and manipulation in the diagnostic imaging setting.

No.	Feature/ Functionality	Description
1	File	Register the required data in the database and search the data
2	MPR	Display the image visualized in 2D/3D and show the image from a selected direction
3	Panorama	Reconfigure the panoramic and cross-sectional images and draw the nerve in the panoramic image
4	Implant	Display the Implant Model registered in a database and virtually place implants in the ideal position
5	TMJ	Display the 2D/ 3D images for a TMJ field
6	Orthodontic	Display a 2D image for horizontal symmetry check
7	3D Ceph	Provide the cephalometric analysis and surgical simulation functions
8	Face Simulation	Map a 3D photo to the entered volume and compare the resultant image of a surgical simulation conducted in 3D Ceph against the existing images
9	Super imposition	Display two different volumes on one screen
10	Endoscopy	Provide a virtual endoscopic function for airway observation
11	Report	Create the patient report

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

Will3D is a software application used for the display and 3D visualization of medical image files from scanning devices, such as Dental CT scanner. It is intended for use by radiologists, clinicians, referring physicians and other qualified individuals to retrieve, process, render, review, store, print, assist in diagnosis, and distribute images utilizing standard PC hardware. Additionally, Will3D is a preoperative software application used for the simulation and evaluation of dental implants, orthodontic planning and surgical treatments.

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 devices which adversely affect safety or effectiveness. Provided below is a table summarizing and comparing the technological characteristics of the Will3D and the predicate devices:

	Proposed Device	Primary Predicate	Reference Predicate
K Number	Not known	K070803	K113543
Model Name	Will3D	InVivoDental™	OnDemand3D^{G2}
Manufacturer	HDX WILL CORP.	Anatomage Inc.	CyberMed Inc.
Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	System, Image Processing, Radiological
Regulatory Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050
Product Code	LLZ	LLZ	LLZ
Classification	II	II	II
Intended Use	Will3D is a software application used for the display and 3D visualization of medical image files from scanning devices, such as Dental CT scanner. It is intended for use by radiologists, clinicians, referring physicians and other qualified individuals to retrieve, process, render, review, store, print, assist in diagnosis, and distribute images utilizing standard PC hardware. Additionally, Will3D is a preoperative software application used for the	InVivoDental is intended for use as a front-end software interface for the transfer of imaging information from a medical scanner such as a Dental CT scanner. It is also intended for use as a planning and simulation software in the placement of dental implants, orthodontics and surgical treatment.	The OnDemand3D^{G2} is intended for use as a software package which loads DICOM images from CT, MR, X-Ray, stores those and provides 3D visualization and 20 analysis, various MPR (Multi-Planar Reconstruction) functions for further rapid and precise diagnosis. 1) Functions for implant surgery planning and fabricating a surgical guide according to the plan 2) Functions to combine

	Proposed Device	Primary Predicate	Reference Predicate
	simulation and evaluation of dental implants, orthodontic planning and surgical treatments.		and show the image data from different modalities such as CT, MRI and PET in one window at the same time 3) Functions to create orthodontic analysis using 3D volume data 4) Functions to sort and save DICOM files, Project Files and 2D image files from different modality [Panorama, Cephalometric, intraoral] under a single patient name
Type of Use	Prescription Use	Prescription Use	Prescription Use
Component	Standalone software	Standalone software	Standalone software
Modality Support	Dental CT scanner	Dental CT scanner	CT, MR, and X-Ray
Operating System	Window 7 or higher and Mac os Yosemite or higher	Windows XP and Windows 7	Window XP/Vista/7/8
Image Communication Standard	DICOM	DICOM	DICOM
Feature/ Functionality	File, MPR, Panorama, Implant, TMJ, Orthodontic, 3D Ceph, Face Simulation, Superimposition, Endoscopy, and Report	Section (MPR), Volume Render (Endoscopy), Arch Section (Panorama), Implant, Restoration, TMJ, Super Pano, Super Ceph, Superimposition, Gallery, Model, 3D Analysis (3D Ceph), Orthodontic, MD studio, Report, and Stitching	File, MPR, Panorama, Implant, TMJ, 3D Ceph, Orthodontic, Face Simulation and Report

Non-Clinical Test Summary

Will3D 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]

Will3D has the similar technical characteristics with the predicate devices. These devices are a dental imaging software program which provides 3D visualization that are reconstructed data from DICOM files.

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. However, in terms of features and functionality, the subject device differs from the primary predicate device, and includes features and functionality not found in the primary predicate, such as File and Face Simulation. To address these differences, OnDemand3D^{G2} was introduced as the reference predicate.

In addition, these technological differences do not raise different questions of safety and effectiveness

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 Will3D is substantially equivalent in safety and effectiveness to the predicate devices as described herein.