Hdx Will Corp.
℅ Kim In-Young
Staff
#105, 106, 201, 202, 203, 204, 38, Osongsaengmyeong 4-ro,
Osong-eup, Heungdeok-gu
Cheongju-si, Chungcheongbuk-do 28161
REPUBLIC OF KOREA

December 15, 2021

Re: K211114
Trade/Device Name: Will3D
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 2, 2021
Received: November 12, 2021

Dear Kim In-Young:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K211114

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.

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]

K211114

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

November 2th 2021

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

- Name of Manufacturer: HDX WILL Corp.
- Address: #105, 106, 201, 202, 203, 204, 38, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea
- Contact Person: In Young Kim / Staff
- Telephone No.: +82-43-710-7318
- Fax No.: +82-43-710-7312
- Email Address: kiy@iwillmed.com
- Registration No.: 3013511605

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

Device Name	Will3D
Regulation Number	21 CFR 892.2050
Common/Usual Name	Medical Image Management and Processing System
Regulatory Class	Class II
Product Code	LLZ
Classification Name	System, Image Processing, Radiological
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

K170180	HDX WILL CORP.	Will3D

There are no significant differences between the Will3D and the predicate device that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, and technical characteristics

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

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

No.	Feature / Functionality	Description
1	Authentication	Software user authentication process function
2	License	Software license check function
3	Main	Software configuration and execution function
	View	
4	File	Register/search the data desired by the user in the database and load the selected data
5	OTS DICOM	Scan, organize image files and convert from software to DICOM image files, process offline media, and send images over a network connection
6	MPR	Display the image visualized in 2D/3D and show the image from a selected direction A function that visualizes the input DICOM image in 2D/3D and outputs it on the screen, allowing the user to view the image from the desired direction.
7	Panorama	Reconfigure the panoramic and cross-sectional images and draw the nerve in the panoramic image
8	Implant	Display the Implant Model registered in a database and virtually place implants in the ideal position
9	TMJ	Display the 2D/3D images of the TMJ field on the screen and provide an interface to easily observe the TMJ area
10	3D Ceph	Provide the cephalometric analysis and surgical simulation functions
11	Face Simulation	A surface model can be created from the input volume

		and 2D photo can be mapped, and the 3D photo created in this way or the 3D photo created by the equipment can be mapped to the input volume. In addition, the function of comparing the image result of surgical simulation performed by 3D Ceph with the existing image.
12	Super imposition	Visually compare and observe changes before and after surgery by outputting two different volumes on one screen
13	Endoscopy	Provide a virtual endoscopic function for airway observation
14	Report	Create the patient report
Common		
15	View Tool	'View' motion control function
16	Measure Tool	Measure function
17	Common Tool	Commonly used functions such as project saving, printing, screen capture, and software information
18	OTF Tool	Adjust the color, transparency, and color range of Volume Rendering video
Engine		
19	MPR Engine	Generate MPR image
20	VR Engine	Create Volume Rendering and Surface Rendering images (*VR means Volume Rendering)
21	OTS 3D Rendering	Create a 2D/3D screen with texture mapping, special effects, and other visual functions

6. 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. Determination of Substantial Equivalence

Summary of technological characteristics of the device compared to the predicate device. [21 CFR 807.92(a)(6)]

a) Technological Characteristics

	Subject Device	Predicate Device	SE Note
Model Name	Will3D	Will3D (K170180)	-
Manufacturer	HDX WILL CORP.	HDX WILL CORP.	-
K Number	K211114	K170180	-
Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	Same
Regulatory Number	21 CFR 892.2050	21 CFR 892.2050	Same
Product Code	LLZ	LLZ	Same
Classification	II	II	Same
Indication for 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 simulation and evaluation of dental implants, orthodontic planning and surgical treatments.	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.	Same
Type of Use	Prescription Use	Prescription Use	Same
Component	Standalone software	Standalone software	Same
Modality Support	CT image data	CT image data.	Same
Operating System	Window 7 or higher and Mac os Yosemite or higher	Window 7 or higher and Mac os Yosemite or higher	Same

	Subject Device	Predicate Device	SE Note
Model Name	Will3D	Will3D (K170180)	-
Image Communication Standard	DICOM	DICOM	Same
Feature/ Functionality	- File - MPR - Panorama - Implant - TMJ - 3D Ceph - Face Simulation - Super imposition - Endoscopy - Report	- File - MPR - Panorama - Implant - TMJ - Orthodontic - 3D Ceph - Face Simulation - Super imposition - Endoscopy - Report	Same

b) Differences between Subject and Predicate Devices

The Will3D is substantially equivalent to the predicate device identified above with respect to intended use and technological characteristics. From the information provided in table above, it is understood that the subject device does not introduce any new technology and/or indications of use. Therefore, the Will3D is considered substantially equivalent to the predicate device.

8. Non-Clinical Test Summary

The 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: “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued on May 11, 2005.”
Cybersecurity information is provided in accordance with FDA guidance: “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, issued on October 2, 2014”

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

The Will3D has same indications for use and technical characteristic to the predicate device. The differences in technological characteristics do not raise different questions of safety and effectiveness. In addition, performance testing conducted demonstrate that the subject device is as safe as effective as the predicate.
Therefore, the subject device is substantially equivalent to the predicate device.