December 19, 2019

3D Industrial Imaging Co., Ltd.
% Sanglok Lee
Manager
Wise Company Inc.
#1005, 11-19, Gamasan-ro 27a-gil
Guro-Gu, 08301
REPUBLIC OF KOREA

Re: K183676
Trade/Device Name: DentiqAir
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: November 8, 2019
Received: November 13, 2019

Dear Sanglok 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. 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,

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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name

Indications for Use *(Describe)*

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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3D Industrial Imaging Co. Ltd

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1 Gwanak-ro, Gwanak-gu, Seoul, Republic of Korea (08826)

510(k) Summary – Traditional 510(K)

The assigned 510(k) Number: K183676

01. Date of Submission: 2019.11.08

02. Applicant / Submitter

3D Industrial Imaging Co., Ltd.
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03. Submission Correspondent

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04. Proposed Device Identification

Device Identification and Regulatory information

Proprietary Name: DentiqAir
Common/Usual Name: Radiological Visualization Software for Diagnosis and Treatment Planning
Classification Name: System, Image Processing, Radiological
Regulation Description**:** Picture archiving and communications system
Product Code: LLZ
Regulation Number: 21 CFR 892.2050
Classification Class: Class II Product

Indications for use:

DentiqAir is a software application for the visualization and segmentation of imaging information of the oral-maxillofacial region. The imaging data originates from medical scanners such as CT or CBCT scanners.
The dental professionals' planning data may be exported from DentiqAir and used as input data for CAD or Rapid Prototyping Systems.

05. Predicate Device Identification

- Reference predicate device
510(k) Number: K110430
Device Name: Dolphin Imaging
Manufacturer: PATTERSON DENTAL SUPPLY, INC

- Primary predicate device
510(k) Number: K133320
Device Name: SICAT Function
Manufacturer: SICAT GmbH & Co, KG

06. Device Description

DentiqAir is a pure software device applied for the visualization and segmentation of imaging information of the ear-nose-throat (ENT) region and oral-maxillofacial region.
The imaging data originates from medical scanners such as CT or Cone Beam – CT (CBCT) scanners. This information can be complemented by the imaging information from optical impression systems.
The medical professionals' input information and planning data may be exported from DentiqAir to be used for CAD or Rapid Prototyping Systems.

07. Technological Characteristics:

DentiqAir requires Windows 7 64 bit OS or above. To ensure proper operation, we recommend installing the subject device on a system with the following specifications or higher.

Item	Specifications
Processor	Intel i3 Dual Core
System Memory	2 GB
HDD	2 GB free hard disk space
Graphics Card	Graphics cards compatible with DirectX 10.1 or Higher
Display	1600 x 900 or Higher

Table 1. Minimum PC Specification Requirements for DentiqAir.

08. Substantially Equivalent

DentiqAir has the same intended uses, principle of operation and similar technical characteristics and functionality as predicate devices.

Feature name	**Subject Device**	**Reference predicate Device**	**Primary predicate Device**	**SE Decision**
Device Name	DentiqAir	Dolphin Imaging	SICAT Function	-
Common/Usual Name	Radiological Visualization Software for Diagnosis and Treatment Planning	Not available	Radiological Visualization Software for Diagnosis and Treatment Planning	-
510K number	-	K110430	K133320	-
Classification	Regulation number: 21 CFR 892.2050 Product code: LLZ	Regulation number: 21 CFR 892.2050 Product code: LLZ	Regulation number: 21 CFR 892.2050 Product code: LLZ	Equivalent with primary and reference device
Manufacturer	3D Industrial Imaging Co. Ltd	PATTERSON DENTAL SUPPLY, INC.	SICAT GmbH & Co, KG	-
Supported anatomic areas	Maxilla, Mandible	Maxilla, Mandible	Maxilla, Mandible	Equivalent with primary and reference device
Indications for Use				
Indications for Use	DentiqAir: DentiqAir is a software application for the visualization and segmentation of imaging information of the oral-maxillofacial region. The			Equivalent with

	imaging data originates from medical scanners such as CT or CBCT scanners. The dental professionals' planning data may be exported from DentiqAir and used as input data for CAD or Rapid Prototyping Systems. Intended Use Statement of 510(k) Summary K110430: "Dolphin Imaging software is designed for use by specialized dental practices for capturing, storing and presenting patient images and assisting in treatment planning and case diagnosis. Results produced by the software's diagnostic and treatment planning tools are dependent on the interpretation of trained and licensed practitioners." Indications for Use Statement of 510(k) Summary K133320: SICAT Function is a software application for the visualization and segmentation of imaging information of the oral-maxillofacial region. The imaging data originates from medical scanners such as CT or CBCT scanners. It is also used as a software system to aid qualified dental professionals with the evaluation of dental treatment options. The dental professionals' planning data may be exported from SICAT Function and used as input data for CAD or Rapid Prototyping Systems			primary device
contraindications	none	unknown	none	Equivalent with primary device
Medical Data Viewing				
Data types visualized	3D volume data, optical impressions	3D volume data, 2D radiological x-ray data, images and photographs	3D volume data, optical impressions, jaw motion tracking data	Equivalent with primary and reference device
Imaging data visualization region	ENT region including the oral-maxillofacial region	ENT region including the oral-maxillofacial region	Oral-maxillofacial region	Equivalent with primary and reference device
Viewing Modes				
Orthogonal slices	Axial, coronal, sagittal	Axial, coronal, sagittal	Axial, coronal, sagittal	Equivalent with primary and reference device
Special Dental View: Panoramic	No	Yes	Panoramic view (ray sum) based on a	DentiqAir does not support

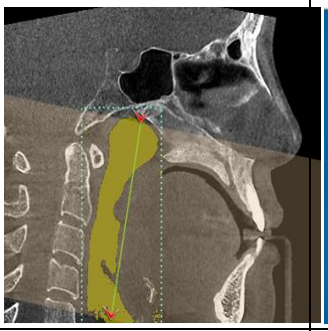
View			panoramic curve. Panoramic curve can be manually adjusted.	Panoramic View.
Special dental view: Cephalometric View	No	Yes	No	Equivalent with primary device
Special dental views: TSA and LSA	Single transversal slices are generated.	Single transversal slices are generated.	Transversal slice (TSA) and longitudinal slice (LSA), both with respect to panoramic curve.	Equivalent with reference device
3D volume rendering	Yes, volume rendering using a standard and well established ray-casting algorithm with integration along rays, and volume rendering utilizing standard shader based slicing algorithms available on typical consumer graphics hardware.	Yes	Yes	Equivalent with primary and reference device
3D surface rendering of volume data	Yes, using a standard and Well established front-to-back ray-casting algorithm with an iso-surface threshold.	Yes	No	Equivalent with reference device
Volume Data Navigation and Manipulation				
View manipulating tools	Zoom, Pan, Change of orientation	Yes	Zoom, Pan, Change of orientation	Equivalent with primary and reference device
Color manipulating tools	Brightness, Contrast	Yes	Brightness, Contrast	Equivalent with primary and reference device

Scrolling through slices	For all slices(without panoramic slicing window)	Yes	For all slices (including panoramic slicing window)	Equivalent with primary and reference device but DentiqAir does not support panoramic slicing window
3D volume Clipping	Yes, Features and Algorithms identical to SICAT Function	Yes	Yes	Equivalent with primary and reference device
Measurements				
Length measurement	Yes	Yes	Yes	Equivalent with primary and reference device
Area measurement	No	Yes	No	Equivalent with primary device
Angle measurement	Yes	Yes	Yes	Equivalent with primary and reference device
Overall Length Measurement Accuracy	100 μm	Unknown	100 μm	Equivalent with primary device
Overall Angular Measurement Accuracy	1 degree	Unknown	1 degree	Equivalent with primary device
Segmentation of Anatomical Structures				

Segmentation of anatomical structures	Yes, using a segmentation wizard. Algorithm: Water Shed (a type of graph-cut algorithm)	Yes Segmentation algorithm is unknown	Yes, using a segmentation wizard. Algorithm: Water Shed (a type of graph-cut algorithm)	Equivalent with primary and reference device
Airway Segmentation	Airway Segmentation of the Airway using the segmentation wizard.	Yes Segmentation algorithm is unknown	No	Equivalent with reference device
Segmentation of mandible and fossa	Yes, using a segmentation wizard. Algorithm: Water Shed (a type of graph-cut algorithm)	No	Yes, using a segmentation wizard. Algorithm: Water Shed (a type of graph-cut algorithm)	Equivalent with primary device
Mesh texturing of the segmented Airway	The Airway is texturized by a standard algorithm. Or The Airway is texturized by the cross-sectional	Yes	No	Equivalent with reference device
Optical Impression Data Visualization				
Optical impression (maxilla, mandible, or a part thereof)	Optical impression (maxilla, mandible, or a part thereof) Polygonal mesh in 3D view, cut through polygonal mesh (contour) in slice view	No	Optical impression (maxilla, mandible, or a part thereof) Polygonal mesh in 3D view and panorama view, cut through polygonal mesh (contour) in slice view	Equivalent with primary device
Optical impression name	No	No	A list view in a dedicated toolbar contains the names of all loaded optical	Equivalent with reference device

			impressions.	
Show/Hide an optical impression	Yes Visibility applies to all views simultaneously.	No	Yes Visibility applies to all views simultaneously.	Equivalent with primary device
Optical Impression Data Manipulation				
Registration of surface data (from optical impressions) to volume data	Semi-automatic, using user specified reference points.	No	Semi-automatic, using user specified reference points.	Equivalent with primary device
Fine tuning the accuracy of the registration	Yes, Restart of the registration with a different set of reference points and Move/Rotate in MPR cross-section image. (Axial/Sagittal/Coronal)	No	Restart of the registration with a different set of reference points.	Equivalent with primary device
Delete	Yes	No	Yes	Equivalent with primary device
I/O				
Volume Data Import	DICOM	DICOM	DICOM	Equivalent with primary and reference device
Optical surface data/optical impression import	Standard STL format	No	Standard STL format and proprietary SSI or SIXD container format.	DentiqAir support only STL Format
Data Import/Export Data Compression	A “Project” consisting of planning data (including segmentation information), volume data, and optical surface data may be exported and imported in a 3DII proprietary format.	No	A “study” consisting of planning data (including segmentation information), volume data, jaw motion	Equivalent with primary device

			data and optical surface data may be exported and imported in a SICAT proprietary format. Lossless ZIP compression	
Export of data for CAD and rapid proto-typing	Yes	No	Yes	Equivalent with primary device
Misc. functions				
Soft tissue simulation with photo mapping	No	Yes	No	Equivalent with primary device
Cross sections in Multiple Planar View (MPV)	No	Yes	No	Equivalent with primary device
Volume stitching: Combine two separate volumes into one	No	Yes	No	Equivalent with primary device
2D facial photo wrap onto volume	No	Yes	No	Equivalent with primary device
Volume-to-volume Superimpositio n	No	Yes	No	Equivalent with primary device
3D nerve marking	No	Yes	No	Equivalent with primary device
Generate panoramic radiographs	No	Yes	Yes	DentiqAir does not support Generate panoramic

				radiographs
Generate cephalometric radiographs	No	Yes	No	Equivalent with primary device
Create animated movies with automated scripts	No	Yes	No	Equivalent with primary device
Design and print handout reports	No	Yes	No	Equivalent with primary device
Image export to other application	No	Yes	Yes	DentiqAir can't export images to other application.
Main Functions				
Three-dimensional airway segmentation and analysis in the ear-nose throat-region	Yes 	Yes 	No	Equivalent with reference device
Airway Visualization	3D surface rendering	3D surface rendering	No	Equivalent with reference device
Airway Analysis: Calculation of airway volume	Yes	Yes	No	Equivalent with reference device
Airway Analysis: Calculation of the airway cross section dimensions	Yes	Yes	No	Equivalent with reference device

Airway Analysis: Calculation of the position and size of the area with minimum cross section in airway	Yes	Yes	No	Equivalent with reference device
Simulation of orthodontic procedures, osteotomies and distraction	No	Yes	No	Equivalent with primary device
Cephalometric analysis	No	Yes	No	Equivalent with primary device
TMJ analysis	Yes	Yes	Yes	Equivalent with primary and reference device
3D implant treatment planning and simulation	No	Yes	No	Equivalent with primary device
Programming Language				
	C# and C++	Unknown	C# and C++	Equivalent with primary device
System Requirements				
Material	Pure software device	Pure software device	Pure software device	Equivalent with primary and reference device
Supported PC formats	Windows	Windows	Windows	Equivalent with primary and reference device

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PC Hardware Requirements (Minimum)	CPU : Intel i3 Dual Core RAM : 2 GB HDD : 2 GB free space Graphic card that supports DirectX 10.1 Monitor: 1600 x 900 pixels resolution Input devices: Keyboard, mouse	Minimum Imaging Requirements (Rev 05/15) CPU : Intel® Core 2 RAM: 2 GB (4 GB for Dolphin 3D) HDD: 20 GB fee space Video card: resolution 1024 x768 at 24-bit color Monitor: 17” Network: none Printer: 720 dpi color inkjet Camera: 3 mega pixel with camera card reader Internet Broadband connection Virus protection coverage DVD-Rom drive required Scanner: 150dpi for x-rays, 300dpi for photos	CPU : 1 GHz RAM : 1 GB HDD : 5 GB free space Video card: Dedicated, 128 MB video memory Shader Model 3 "INTZ"-Surfaces Current driver Monitor: 1280 x 1024 pixels resolution Network: Ethernet, 100 Mbit/s Input devices: Keyboard, mouse	Equivalent with primary and reference device
PC Software Requirements (Minimum)	Operating System : Windows 7,8 and 10(64bit)	Operating system: Windows Vista or higher Word processor: MS-Word 2003 or higher	Operating system: Windows XP (32 bit) with SP3 Windows Vista (32 bit or 64 bit) Windows 7 (32 bit or 64 bit) Windows 8 (32 bit or 64-bit)	Equivalent with primary and reference device
User Interface	Monitor, Mouse, Keyboard	Monitor, Mouse,	Monitor, Mouse,	Equivalent with

		Keyboard	Keyboard	primary and reference device

The missing features of DentiqAir are orthodontic procedures, osteotomies and distractions, Panoramic view, Generate panoramic radiographs, Area measurement, cephalometric analysis, Optical impression name and 3D implant treatment planning and simulation and Misc. functions as identified in the comparison table above. Primary device, SICAT Function supports STL,SSI,SIXD Format, while DentiqAir only supports STL Format. This does not have an impact on the safety and effectiveness of DentiqAir concerning the visualization and segmentation of imaging information and the evaluation of treatment options.

DentiqAir has also the same function to aid qualified dental professionals with the evaluation of dental treatment options as primary device (SICAT Function). Also, DentiqAir has also the same function (Analysis in the ear-nose-throat region, particularly the airway analysis, including the three-dimensional airway segmentation and visualization) as reference predicate device (Dolphin Imaging). Performance testing has been used to validate the safety and effectiveness of the DentiqAir segmentation features in comparison to the predicate devices

09. Non clinical Testing

In order to establish the performance, functionality and reliability characteristics of the subject device, SW verification and validation testing activities such as code review, module review, integration review, and dynamic tests were conducted in accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (Issued on May 11, 2005).

Also the following performance tests were conducted to verify the performance of the subject device and find out any limitations.
- Accuracy test for measurement made in the subject device from loaded CT datasets using phantom by comparing the true values of the phantom and the measured values (Length, Angle, HU, Volume) in the subject device. The P/F criteria for Length, Angle, HU was less than 2% average and maximum absolute difference. The P/F criteria for Volume was less than True Value and more than Dolphin Imaging average.

The testing results support that the subject device is substantially equivalence to the predicate or reference devices.

10. Clinical Testing

Clinical testing is not a requirement and has not been performed.

11. Conclusion

The subject device and the 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. Therefore, it is our opinion that the DentiqAir described in this submission is substantially equivalent to the predicate devices.