May 23, 2022

3D ONS, Inc.
% DongHa Lee
Regulatory Affairs Consultant
KMC, Inc.
Room no. 1709, 123, Digital-ro 26-gil, Guro-gu
Seoul, 08390
KOREA

Re: K221000
Trade/Device Name: ON3D
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 30, 2022
Received: April 4, 2022

Dear DongHa 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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT 8B: Division of Radiological Imaging
and Electronic Products
OHT8: Office of 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)*

K221000

Device Name
ON3D

Indications for Use *(Describe)*

ON3D is software that 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 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.

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510(k) Summary (K221000)

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

Date: May 9, 2022

1. Applicant / Submission Sponsor

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2. Submission Correspondent

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3. Device Identification

- Trade/Proprietary Name: ON3D
- Classification Name: Medical image management and processing system
- Classification Regulation: 21 CFR 892.2050
- Product Code: LLZ
- Device Class: 2

4. Predicate Devices

Manufacturer	Patterson Dental Supply, Inc.
Device Name	Dolphin Imaging
510(k) number	K110430
Product Code	LLZ

5. Device Description

ON3D is a stand-alone software that captures, stores and present patient data in volumetric views to assist specialized dental practitioners for treatment and surgical planning and case

diagnosis. With a user-friendly graphical user interface, ON3D makes processing 3D data extremely simple, enabling dental specialists from a wide variety of disciplines to diagnose, plan treatment, document and present cases. ON3D allows visualization and analysis of craniofacial anatomy from data produced by 3D dataset format, such as cone beam computed tomography (CBCT), and it creates a personalized 3D model for the dentists with the optimal pre-surgical information necessary for the surgeries. It features tools for the manipulation and analysis of volumetric datasets, and the images are easily oriented and rotated. Tissue density thresholds can be adjusted for detailed views of craniofacial anatomy. ON3D product features include 3D airway analysis, multiple planar views, volume stitching, 2D/3D facial photo wrap onto the volumetric model, 3D neural canal markings, TMJ analysis, 3D/2D measurements, export images to other applications, such as STL or PLY, and more.

6. Indication for use

ON3D is software that 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 dental practitioners.

7. Substantial Equivalence

ON3D is substantially equivalent to the predicate devices, Dolphin Imaging (K110430). The following comparison table is presented to demonstrate substantial equivalence.

-	Subject Device	Predicate Device	Remarks
510(k) Number	K221000	K110430	-
Trade/Device Name	ON3D	Dolphin Imaging	-
Manufacturer	3D ONS, Inc.	Patterson Dental Supply, Inc. (doing business as Dolphin Imaging & Management)	-
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Same
Regulatory Class	Class II	Class II	Same
Product Code	LLZ	LLZ	Same
Intended Use	ON3D is software that 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 dental practitioners.	Dolphin Imaging is software that 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 dental practitioners.	Same
Standalone Software	Yes	Yes	Same

Operation System	Windows	Windows or Mac OS	Same
User Interface	Mouse, Keyboard	Mouse, Keyboard	Same
Image rendering	2D and 3D	2D and 3D	Same
Image manipulation	Preview, Rotate, Enhance, Zoom, Brightness, Contrast, Sharpness	Preview, Rotate, Enhance, Zoom, Brightness, Contrast, Sharpness	Same
Basic image measurement	Distance, angle	Distance, angle	Same
3D airway analysis	Yes	Yes	Same
Cross sections in multiple planar views (MPV)	Yes	Yes	Same
Volume orientation control	Yes	Yes	Same
Volume stitching	Combine two separate volumes into one	Combine two separate volumes into one	Same
Volume-to-volume superimposition	Yes	Yes	Same
Cephalometric tracing and analysis	None	Manual point picking and automatic structure templates Software provides predefined landmarks and tracing structures. Can trace on 3D volume and 2D photo.	Difference does not affect SE (Note 1.)
3D/2D analysis	Provide both 3D and 2D analysis. 3D analysis is performed on 3D volume. 2D analysis is performed on a pre-determined plane (mid-sagittal plane) using 3D landmarks that are projected on the 2D plane.	Provide both 3D and 2D analysis. 3D analysis is performed on 3D volume. 2D analysis is performed on 2D photo or x-ray. Standard orthodontic tracing analyses and user-configurable analysis:	Difference does not affect SE (Note 2.)
3D neural canal marking	Yes	Yes	Same
TMJ analysis	Yes	Yes	Same
Surgical planning and simulation	Orthodontic and orthognathic applications using maxillary, mandible, and chin and cheek cuts. User can translate, rotate the cuts.	Orthodontic and orthognathic applications using maxillary, mandible, and chin and cheek cuts. User can translate, rotate the cuts.	Same
Distinguish biological structures via their radiolucency	Yes	Yes	Same
Soft tissue deformation	Yes. 2D and 3D	Yes. 2D and 3D	Same
Photo wrapping	Can wrap 2D and 3D photos on volume image	Can wrap 2D and 3D photos on volume image	Same
3D Dental Implant	No	Yes	Difference

and TAD treatment planning and simulation			does not affect SE (Note 3.)
Generate panoramic radiographs	Yes	Yes	Same
Scanner connection	Yes	Yes	Same
Export images/data to other applications	Yes.	Yes	Same
DICOM support	Yes	Yes	Same

(Note 1.) Cephalometric tracing and analysis

: Although the subject device can display a simple outline of mandible and maxilla by enabling the users to draw lines by connecting landmarks selected for the analysis, the subject device does not have cephalometric tracing and analysis feature. This difference does not raise any risks in the safety and effectiveness of the device for the proposed intended use as it is demonstrated in the software verification and validation documents, and performance test reports.

(Note 2.) 3D/2D analysis

: Both devices provide both 3D and 2D analysis. Although the 3D analysis method is the same, the input image for 2D analysis is different. The predicate device performs 2D analysis on 2D photo or x-ray but the subject device performs 2D analysis on a pre-determined plane (mid-sagittal plane) of the 3D volume using landmarks (3D) that are projected on the 2D plane. The subject device uses 3D image data only and does not use 2D photo or x-ray images (cephalogram). Although there is no 2D image data input, the predicate device generates 2D images from the 3D volume and perform 2D analysis on the generated 2D images. This difference does not raise any risks in the safety and effectiveness of the device for the proposed intended use as it is demonstrated in the software verification and validation documents, and performance test reports.

(Note 3.) Dental Implant and TAD treatment planning and simulation

: The subject device does not have applications for dental implant and TAD treatment planning and simulation. This difference does not raise any risks in the safety and effectiveness of the device for the proposed intended use.

8. Software Verification and Validation

The Software Verification and Validation were performed to assess the effectiveness of the medical purpose software in accordance with IEC 62304 standard requirements. The testing was performed at the system level, the integration level, and the unit level tests.

9. Performance Testing – Bench Testing

The performance testing (bench testing) was performed as the software system-level test to assess the effectiveness of the device (stand-alone software) performance including each UI as Open the study in the Worklist, Basic function for Viewer, Button function, Hot-key function, Main function simulation, Environmental setting, System setting, Worklist.

10. Conclusion

In substantial equivalence discussion between the subject device and the predicate device, there are the same characteristics such as product code, regulation number, intended use, prescription-only indication, product main features/functions, operation environment and operation system. Although there are some different characteristics (such as cephalometric tracing and analysis, input image for 2D analysis, and absence of the dental implant and TAD treatment planning and simulation), the safety and performance test results provide a reasonable assurance of safety and effectiveness with respect to the intended users and the conditions of use prescribed, recommended, or suggested in the labeling of the device.

Therefore, we believe that the subject device does not raise concerns in safety and effectiveness for the proposed intended use and that the subject device is substantially equivalent to the predicate device.