December 3, 2021

Prodigident, Inc.
% Andrii Gromov
Chief Executive Officer
1350 Lake Street, Suite 1B
ROSELLE IL 60172

Re: K210241
Trade/Device Name: ImplaStation
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: September 26, 2021
Received: November 1, 2021

Dear Andrii Gromov:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210241

Device Name
ImplaStation

Indications for Use *(Describe)*
ImplaStation is stand-alone software designed for trained qualified dental practitioners, including dentists and dental technicians.
The software can be used to visualize a patient's medical image dataset output in DICOM format from third-party CT/ CBCT scanners.
ImplaStation is intended for use as a pre-operative tool for the dental implant(s) positioning based on the CT/CBCT image dataset aligned to optical 3D surface scan(s) and for the surgical guide planning result file creation. The surgical guide can be manufactured using a planning result file when used as input to 3D manufacturing systems.
3D manufacturing is out of ImplaStation software control, depends on many external factors and lie within the sole responsibility of the user.

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 K210241

I. SUBMITTER

PRODIGIDENT, Inc.
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United States

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E-mail: andrey.gromov@prodigident.com

Contact Person: Andrii Gromov, CEO
Date Prepared: December 30, 2020

II. DEVICE

Name of Device:	ImplaStation
510(k) number:	K210241
Common or Usual Name:	Implant Planning and Surgical Guide Creation Software
Classification Name:	Medical image management and processing system
Regulation Number:	21 CFR 892.2050
Regulatory Class:	II
Product Code:	LLZ

III. PREDICATE DEVICE

Name of Device:	CoDiagnostiX Implant Planning Software
510(k) number:	K130724
Common or Usual Name:	Implant Planning and Surgical Guide Creation Software
Classification Name:	Medical image management and processing system
Regulation Number:	21 CFR 892.2050
Regulatory Class:	II
Product Code:	LLZ

This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

ImplaStation is stand-alone software designed for trained qualified dental practitioners.
The key scientific concept (807.92(a)(4)) of the ImplaStation software is the visualization of a patient's medical image data (DICOM file from third-party CT/CBCT scanners) to pre-operative digital implant planning, surgical guide (drill guide) file (output of the pre-operative implant planning) creation.
The data acquired by the optical scanner (scanned surface of the maxilla or mandible) can be aligned to the CT/CBCT reconstruction through a point-based registration technique.
Virtual crown(s) design and nerve tracing can be used as additional tools to assist the specialist during an implant planning process.

The ImplaStation library contains implant, abutment, drill, and sleeve files, which are encrypted files and approved by the corresponding implant manufactures. The software allows designing the surgical guide (drill guide) file and exporting the generated file to a 3rd party external system for manufacturing.
The device has no patient contact, nor does it control any life-sustaining devices.

Warning: Pathways of imaged nerves cannot be used as sole information for the clinician to make clinical decisions.

V. INDICATIONS FOR USE

ImplaStation is stand-alone software designed for trained qualified dental practitioners, including dentists and dental technicians.
The software can be used to visualize a patient's medical image dataset output in DICOM format from third-party CT/CBCT scanners.
ImplaStation is intended for use as a pre-operative tool for the dental implant(s) positioning based on the CT/CBCT image dataset aligned to optical 3D surface scan(s) and for the surgical guide planning result file creation. The surgical guide can be manufactured using a planning result file when used as input to 3D manufacturing systems.
3D manufacturing is out of ImplaStation software control, depends on many external factors and lie within the sole responsibility of the user.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The ImplaStation software covered in this submission is based on the same technological characteristics and has the same intended use as the legally cleared coDiagnostiX Implant Planning Software (predicate device).

Table 1. Identification of Similarities/Differences in Technological Characteristics between the ImplaStation software and coDiagnostiX Implant Planning Software (predicate device):

No	Feature	Proposed Device ImplaStation	Predicate Device coDiagnostiX Implant Planning Software (K130724)
1.	Indications for Use	ImplaStation is stand-alone software designed for trained qualified dental practitioners, including dentists and dental technicians. The software can be used to visualize a patient's medical image dataset output in DICOM format from third-party CT/CBCT scanners. The software aids the user in the guided implant surgery planning to provide a design of dental restorative solutions. ImplaStation is intended for use as a pre-operative tool for the dental implant(s) positioning based on the CT/CBCT image dataset aligned to optical 3D surface scan(s) and for the surgical guide file creation, and export of the created file to an external system for manufacturing.	CoDiagnostiX is an implant planning and surgery planning software tool intended for use by dental professionals who have appropriate knowledge in dental implantology and surgical dentistry. This software reads imaging information output from medical scanners such as CT or DVT scanners. It allows pre-operative simulation and evaluation of patient anatomy and dental implant placement. For automated manufacturing of drill guides in the dental laboratory environment, the coDiagnostiX can provide printouts of template plans for the creation of surgical templates using a manually operated gonyX table.
2.	Input Source	CT / CBCT scanner	CT / CBCT, DVT scanners

No	Feature	Proposed Device ImplaStation	Predicate Device coDiagnostiX Implant Planning Software (K130724)
3.	Input Data	DICOM, .stl files	DICOM, .stl files
4.	Output Data	.stl file	.stl file
5.	Minimum system hardware and software requirements	macOS X 10.9 or newer; OS - Windows 7, 64-bit; Central Processing Unit (CPU) - Intel Core i3; Memory (RAM) - 2GB; Graphics Card - Intel HD Graphics 615; Intel HD Graphics 620; NVIDIA GeForce 1GB, HDD - 3GB of free space, Monitor resolution - 1600 x 900 pixels	macOS X 10.9 or newer; OS - Windows 7, 64-bit Central Processing Unit (CPU) - Intel® Core™ 2 Duo processor P8600 Memory (RAM) - 8GB Graphics Card - Not specified HDD – 128 GB of free space Monitor resolution - 1680 x 1050 pixels
6.	Image registration (alignment)	The scanned surface data acquired by the optical/intraoral scanner can be aligned to the CT/CBCT reconstruction through a point-based registration technique	The scanned surface data acquired by the optical/intraoral scanner can be aligned to the CT/CBCT reconstruction through a point-based registration technique
7.	Projects management	Project exporting/importing	Project exporting/importing
8.	Case visualization	2D gray value images 3D model rendering Panoramic mode MPR mode Individual editing of imaging artifacts	2D gray value images 3D model rendering Panoramic mode MPR mode Individual editing of imaging artifacts
9.	DICOM data processing	DICOM segmentation, DICOM to STL conversion	DICOM segmentation, DICOM to STL conversion
10.	STL data processing	System allows to process STL files, group files, fix errors, edit and copy STL files	System allows to process STL files, group files, fix errors, edit and copy STL files
11.	Measurement tool	Distance/Angle	Distance/Angle; Bone density measurement
12.	Nerve tracing	Possible	Possible
13.	Virtual Wax-up	Possible	Possible
14.	Implant Planning tools	Implant, sleeve, drill, abutment, analog, and pin positioning; Custom Implant, Sleeve, Drill, Abutment, and Pin creation; Implant-to-implant, Implant-to-nerve canal, Sleeve-to-Sleeve, and Sleeve-to-STL surface distance/collision warning.	Implant, sleeve, drill, abutment, analog, and pin positioning; Custom Implant, Sleeve, Drill, Abutment, and Pin creation; Implant-to-implant, Implant-to-nerve canal, and Sleeve-to-Sleeve surface distance/collision warning.

No	Feature	Proposed Device ImplaStation	Predicate Device coDiagnostiX Implant Planning Software (K130724)
15.	Surgical guide design	Tooth-supported surgical guide design possible; Gingiva-supported surgical guide design possible; Bone-supported surgical guide design possible; Export of surgical guide design data set possible; Offset, wall thickness and connector thickness setting possible.	Tooth-supported surgical guide design possible; Gingiva-supported surgical guide design possible; Bone-supported surgical guide design possible; Export of surgical guide design data set possible; Offset, wall thickness and connector thickness setting possible.
16.	Surgical protocol design and creation tool	Details protocol: available per implant providing detailed implant, sleeve and surgical protocol information together with images of the planning views; Surgical protocol: The sequence of surgical instruments to be used as specified by the selected guided surgery system (selected manufacturers only)	Details protocol: available per implant providing detailed implant, sleeve and surgical protocol information together with images of the planning views; Surgical protocol: The sequence of surgical instruments to be used as specified by the selected guided surgery system (selected manufacturers only)
17.	Payment model	Pay per use License Fee Annual Fee	License Fee Annual Fee

Guided oral surgery consists of the insertion of dental implants in the exact position, inclination, and depth, through the use of customized tooth-, bone-, or mucosa-supported surgical guides designed with dedicated software and physically realized by three-dimensional (3D) printing.

ImplaStation covered in this submission and the previously cleared coDiagnostiX Implant Planning Software (predicate devices) are meant for use with standard PC hardware and include similar intended use, technology, level of concern and major functionality related to visualization and processing medical image DICOM files, implant planning and surgical guide designing.

It should be noted that in addition to the Implant-to-implant, Implant-to-nerve canal, and Sleeve-to-Sleeve collision warning system, ImplaStation has a Sleeve-to-STL surface distance/collision warning system. The ImplaStation software does not offer tools for bone density measurement. Studies regarding grey values in CBCT data showed that they cannot be standardized and allocated to specific anatomical structures as in CT. Therefore, Hounsfield units used for interpretation of CT data are not applicable for CBCT data and bone density measurements in CBCT are not reliable.

The difference between ImplaStation and coDiagnostiX Implant Planning Software does not raise additional concerns regarding its safety and effectiveness.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Nonclinical Testing:
Nonclinical verification and validation testing were performed to ensure that the ImplaStation subject to this 510(k) Premarket Notification functions as intended. Testing has been carried out in accordance with the FDA guidance document: "*General Principles of Software Validation; Final Guidance for Industry and FDA Staff*", issued on January 11, 2002.

The Prodigident ImplaStation complies with the following standards:
• IEC 62304
• ISO 13485
• ISO 14971
• IEC 80001-2-2
• NEMA PS 3.1 - 3.20

Clinical Testing:
Clinical testing was not needed to support a claim of Substantial Equivalence to the predicate device.

Based on the performance as documented in the non-clinical study, the ImplaStation software was found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. CONCLUSIONS

Based on a comparison of intended use, technical characteristics, principle of operations, features and tools, and the test results, the subject device ImplaStation is found to be substantially equivalent in safety and effectiveness to the predicate device. Intended use and performance is found to be substantially equivalent to the predicate device.