November 14, 2017

Planmeca Oy
% Mr. Lars Moring
Regulatory Affairs Manager
Asentajankatu 6
Helsinki, 00880
FINLAND

Re: K171385
Trade/Device Name: Planmeca Romexis
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 5, 2017
Received: October 10, 2017

Dear Mr. Moring:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171385

Device Name
Planmeca Romexis

Indications for Use *(Describe)*

Planmeca Romexis is a medical imaging software intended for use in dental and medical care as a tool for displaying and visualizing dental and medical 2D and 3D image files from imaging devices, such as projection radiography and CBCT. It is intended for use by radiologists, clinicians, referring physicians and other qualified individuals to retrieve, process, render, diagnose, review, store, print, and distribute images of both adult and pediatric patients.

Planmeca Romexis is also a preoperative software application used for dental implant planning. Based on the planned implant position a model of a surgical guide for a guided implant surgery can be designed, The designed data can be exported to manufacture a separate physical product.

Additionally, Planmeca Romexis includes monitoring features for Planmeca devices for maintenance purposes. The software is designed to work as a stand-alone or as an accessory to Planmeca imaging and Planmeca dental unit products in a standard PC. The software is for use by authorized healthcare professionals. Use of the software for implant planning requires that the user has the necessary medical training in implantology and surgical dentistry.

Indications of the dental implants do not change with guided surgery compared to conventional surgery.

Planmeca Romexis is also intended to be used for monitoring, recording, storing and displaying mandibular jaw positions and movements relative to the maxilla.

This device is not indicated for mammography use.

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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PLANMECA

510(k) SUMMARY

DATE

Nov 10, 2017

PRODUCT, CLASSIFICATION NAME

Device name:	Planmeca Romexis
Common name:	System, Image Processing, Radiological
Classification:	Class II
Classification name:	Imaging Processing System, LLZ, 21 CFR 892.2050

SUBMITTED BY

Planmeca Oy
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Phone: +358 20 7795 500
Contact person: Mr. Lars Moring

U.S DESIGNATED AGENT

Planmeca USA Inc.
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Roselle, IL 60172
Phone: (630) 529 2300
Contact person: Brett Hines

DEVICE DESCRIPTION

Planmeca Romexis is a modular imaging software for dental and medical use. It is divided into modules to provide user access to different workflow steps involving different diagnostic views of images. Patient management screen with search capabilities lets users to find patients and identify correct patient file before starting work with a patient. After creating or selecting patient, new images can be acquired using select Planmeca X-ray units.

Planmeca Romexis is capable of processing and displaying 2D images in different formats and 3D CBCT images in DICOM format. 3D CBCT images can be viewed in near real-time multi projection reconstruction (MPR) views. 2D and 3D image browsers are provided to allow user access to relevant images. Typical image enhancement filters and tools are available to assist the user in making diagnosis but original exposure is always kept in the database for reference.

Images can be exported to files or writable media, printed to paper or DICOM media or transferred securely to other users using Planmeca online services. Interfaces to select external software are provided to facilitate exchange of patient information and images or data between Software and 3rd party applications.

INTENDED USE

Planmeca Romexis is a medical imaging software intended for use in dental and medical care as a tool for displaying and visualizing dental and medical 2D and 3D image files from imaging devices, such as projection radiography and CBCT. It is intended for use by radiologists, clinicians, referring physicians and other qualified individuals to retrieve, process, render, diagnose, review, store, print, and distribute images of both adult and pediatric patients.

Planmeca Romexis is also a preoperative software application used for dental implant planning. Based on the planned implant position a model of a surgical guide for a guided implant surgery can be designed, The designed data can be exported to manufacture a separate physical product.

Additionally, Planmeca Romexis includes monitoring features for Planmeca devices for maintenance purposes. The software is designed to work as a stand-alone or as an accessory to Planmeca imaging and Planmeca dental unit products in a standard PC. The software is for use by authorized healthcare professionals. Use of the software for implant planning requires that the user has the necessary medical training in implantology and surgical dentistry.

Indications of the dental implants do not change with guided surgery compared to conventional surgery.

Planmeca Romexis is also intended to be used for monitoring, recording, storing and displaying mandibular jaw positions and movements relative to the maxilla.

- This device is not indicated for mammography use.

EQUIVALENT DEVICES

Primary predicate device:

K123519	Anatomage	InVivoDental

Reference devices:

K061035	Televere Systems	TigerView
K141570	3Shape Medical	Implant Studio
K133320	SICAT	SICAT Function

INTENDED USE COMPARISON

The intended use of Planmeca Romexis is substantially equivalent to that of the predicate device, with few exceptions that do not raise any new or potential safety risks to the user or patient.
The most evident is that Planmeca Romexis includes service managing features for Planmeca devices for maintenance purposes, which are not intended for clinical use.

TECHNOLOGICAL CHARACTERISTICS

A comparison of key software characteristics, including operating environment, functionalities, image files, and other major features was performed. Some general comparison data:

Primary predicate device:

InVivoDental:
Similar characteristics related to managing of 3D image files. Both are meant for use with standard PC hardware and include similar major functionality related to display, processing, visualization and sharing of dental and medical 3D image files, such as multiplanar views, volume rendering view, measurements, implant planning, airways visualization, TMJ module, virtual cephalometric and panoramic images and sharing of image files with a viewer.

Reference devices:

TigerView Professional:
Similar characteristics related to managing of 2D image files. Both are meant for use with standard PC hardware and include similar major functionality related to display, editing, reviewing, storing, printing, and distributing of 2D image files, such as annotations, adjustments, integration with practice management systems and distribution of images in Picture Archiving and Communication System (PACS) environment.

Implant Studio:
Similar characteristics related to implant planning and implant guide designing. Both are meant for use with standard PC hardware and include similar major functionality related to implant planning and guide designing.

SICAT Function:
Similar characteristics related to managing 3D image files such as viewing 2D slice views, 3D volume and surface rendering, segmentation of data, fitting of optical impressions and jaw motion visualization.

Based on the presented technical comparison of the Planmeca Romexis and the predicate device it was concluded that these devices are technically substantially equivalent.
The differences found are not significant as they do not raise any new or potential safety risks to the user or patient or questions related to safety or effectiveness.

NON-CLINICAL TEST RESULTS

The following quality assurance measures were applied to the development of the Software:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance testing (Verification)
- Safety testing (Verification)
- Final acceptance testing (Validation)
- Bench testing to compare with predicate software

Testing confirmed that Planmeca Romexis is stable and operating as designed. Testing also confirmed that Planmeca Romexis has been evaluated for hazards and that the risk has been reduced to acceptable levels.

The non-clinical bench-testing of Planmeca Romexis with predicate software version was performed by comparison of images rendered by Planmeca Romexis and the predicate software version. The results confirm that the software applications are equally effective in performing the essential functions and provide substantially equivalent clinical data.

SUMMARY

Based on the intended use, product, performance, and testing information provided in this notification, the subject device has been shown to be substantially equivalent in technology, functionality, and indicated use to the currently marketed predicate device.