Planmeca Oy   December 2, 2020
℅ Lars Moring
Regulatory Affairs Manager
Asentajankatu 6
Helsinki, 00880
FINLAND

Re: K200572
      Trade/Device Name: Planmeca Romexis
      Regulation Number: 21 CFR 892.2050
      Regulation Name: Picture archiving and communications system
      Regulatory Class: Class II
      Product Code: LLZ
      Dated: October 19, 2020
      Received: October 23, 2020

Dear Lars 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. 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).

<div style="text-align:center">Sincerely,</div>

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)*
K200572

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 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 objects can be exported to manufacture a separate physical product.

Planmeca Romexis is also a preoperative software for simulating / evaluating surgical treatment options.

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

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 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. Use of the software for surgical treatment planning requires that the user has the necessary medical training in maxillofacial surgery.

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

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.

510(k) SUMMARY

DATE

October 19, 2020

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
Asentajankatu 6
00880 Helsinki, Finland
Phone: +358 20 7795 500
Contact person: Mr. Lars Moring

U.S DESIGNATED AGENT

Planmeca USA Inc.
2600 Forbs Ave., Hoffman Estates, IL 60192
Phone: (630) 529 2300
Contact person: Ed McDonough

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.

INDICATIONS FOR 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 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 objects can be exported to manufacture a separate physical product.

Planmeca Romexis is also a preoperative software for simulating / evaluating surgical treatment options.

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

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 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. Use of the software for surgical treatment planning requires that the user has the necessary medical training in maxillofacial surgery.

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

EQUIVALENT DEVICES

Primary predicate device:
K123519   Anatomage   InVivoDental

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

Newly added reference device:
K110430   Patterson Dental   Dolphin Imaging

INDICATIONS FOR USE COMPARISON

The indications for use of Planmeca Romexis is substantially equivalent to that of the predicate devices, 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:

	Planmeca Romexis	InVivoDental (K123519)
Operating environment	standard PC hardware	standard PC hardware
Functionalities	Viewing, enhancing, processing, archiving, printing and sharing images	Retrieve, process, render, review, store, print, assist in diagnosis, and distribute images
Image files	2D, 3D	3D
Major features	Multiplanar views	Section and Multislice View Operations
	3D volume rendering view	Volume Rendering of scan data
	Linear, angular, area and volumetric measurements	Linear, Angular, Circumferential, Area and Volumetric Measurements
	Implant Planning module	Implant, Abutment and Restoration Treatment Planning
	Airway volume measurement	Quick Airway Volume Measurement and Evaluation
	TMJ module	TMJ Applications
	Virtual Cephalometric image	SuperCeph
	Virtual Panoramic image	SuperPano
	Software Viewer	InVivo Viewer

Reference devices:

	Planmeca Romexis	TigerView Professional (K061035)
Operating environment	standard PC hardware	standard PC hardware
Functionalities	Viewing, enhancing, processing, archiving, printing and sharing images	acquire, display, edit, review, store, print, and distribute images
Image files	2D, 3D	2D

	YES	YES
Integration with Practice Management Systems	YES	YES
Integration with hospital PACS systems	YES	YES
Features	image processing, brightness & contrast, crop, annotations	resize, adjust contrast, crop, annotate

	Planmeca Romexis	**Implant Studio (K141570)**
Operating environment	standard PC hardware	standard PC hardware
Functionalities	Viewing, 3D data fitting, implant planning, implant guide designing	prosthetic driven implant planning, surgical guide design
Image files	2D, 3D	3D
Major features	Implant guide designing, implant and sleeve libraries	Implant guide designing, implant and sleeve libraries

	Planmeca Romexis	**SICAT Function (K133320)**
Operating environment	standard PC hardware	standard PC hardware
Functionalities	Viewing, enhancing, processing, archiving, printing and sharing images	Visualization and segmentation of imaging information
Visualized data types	2D, 3D, optical impressions, jaw motion data	3D volume data, optical impressions, jaw motion data
Major features	Visualization of 3D images using multi-planar 2D views, 3D volume rendering, 3D surface rendering	Visualization of 3D images using 2D slice views, 3D volume rendering, 3D surface rendering
	Fitting of optical impressions to 3D image	Registration of optical scans to volume data
	Segmentation of the jaws	Segmentation of jaws using wizard
	Visualization of jaw movement data	Visualization of jaw movement data

Comparison table between the subject and newly added reference device:

	Planmeca Romexis	**Dolphin Imaging (K110430)**
Operating environment	Standard PC hardware	Windows OS
Visualized data types	2D, 3D, optical impressions, 3D face photos	2D, digital study models, 3D, 3D face camera photos
Major features	Visualization of 3D images using multi-planar 2D views, 3D volume rendering, 3D surface rendering, airway rendering	Multi-planar visualization, rendering of 3D volume, 3D photo, digital impression, airway
	Linear, angular, area and volumetric measurements	3D-2D measurements: distance, angle, area
	Segmentation of jaws	Segmentation of image data

	Definition of osteotomy planes	Definition of osteotomy planes
	Free movement and rotation of bone fragments.	Treatment simulation by moving skeletal structures

Based on the presented technical comparison of the Planmeca Romexis and the predicate devices 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 versions were performed by comparison of images rendered by Planmeca Romexis and the predicate software versions. 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 devices.