Planmeca Oy
Lars Moring
Regulatory Affairs Specialist
Asentajankatu 6
FI-00880 Helsinki
FINLAND

September 13, 2018

Re: K181576
Trade/Device Name: Planmeca Viso
Regulation Number: 21 CFR 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: August 15, 2018
Received: August 17, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Digitally signed by Jeffrey J. Ballyns -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000569725, cn=Jeffrey J. Ballyns -S
Date: 2018.09.13 16:30:25 -04'00'

for
Robert A. 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)*
K181576

Device Name
Planmeca Viso

Indications for Use *(Describe)*
Planmeca Viso is a system intended to produce two-dimensional (2D) and three-dimensional (3D) digital x-ray images as well as three-dimensional (3D) optical images of the dento-maxillo-facial, cervical spine and ENT (Ear, Nose, and Throat) regions at the direction of healthcare professionals as diagnostic support for pediatric and adult patients.

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.

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510K) SUMMARY

I. SUBMITTER

MANUFACTURER
Planmeca Oy
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Contact person: Lars Moring

U.S. DESIGNATED AGENT
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Roselle, IL 60172
Phone: (630) 894 2300
Contact person : Bob Pienkowski

Date prepared: September 7, 2018

II. PRODUCT, CLASSIFICATION NAME

Name of the device:	Planmeca Viso
Common or Usual Name:	Computed tomography x-ray system
Classification name:	Computed tomography x-ray system (21 CFR 892.1750)
Regulatory Class:	II
Product Code:	OAS
510(k) number:	#K181576

III. PREDICATE DEVICE

Planmeca ProMax 3D Max #K160506

IV. REFERENCE DEVICE

Planmeca ProMax 3D Mid #K103689
RAYSCAN A-EXPERT 3D, #K142247

V. DEVICE DESCRIPTION

The Planmeca Viso -X-ray unit uses cone beam computed tomography (CBCT) to produce three-dimensional (3D) images of the maxillofacial and ENT anatomies. Two dimensional (2D) images are produced with tomosynthesis method (panoramic) imaging) as well as conventional 2D radiography (cephalometric imaging, 2D views). In CBCT a cylindrical volume of data is captured in one imaging procedure. The data consists of several hundred sample images which are taken from different directions to cover a certain pre-programmed target area. These samples are used for 3D reconstruction (using a separate 3D reconstruction PC) that can be viewed in three dimensions using separate workstation and Planmeca Romexis software.

VI. INDICATIONS FOR USE

Planmeca Viso is a system intended to produce two-dimensional (2D) and three-dimensional (3D) digital x-ray images as well as three-dimensional (3D) optical images of the dento-maxillo-facial, cervical spine and ENT (Ear, Nose, and Throat) regions at the direction of healthcare professionals as diagnostic support for pediatric and adult patients.

The Indications for Use (IFU) for the subject device are the same as those for the predicate device.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both devices are 3D CBCT imaging system indicated for imaging dento-maxillofacial-, cervical spine- and ENT-regions and offer a variety of 3D fields of view suitable for each application. Both systems also provide 2D imaging capabilities, predicate device only for panoramic and Planmeca Viso both for panoramic and cephalometric imaging.

Both systems are based on fixed anode X-ray tube and a flat panel detector of the same technology. Pixel sizes of the detector differ but voxel sizes on resulting 3D images are the same." Tube voltage range with Planmeca Viso is wider and ranges up to 120kV, providing users with option to utilize even higher X-ray penetration when necessary.

Table 1: Comparison with predicate device

	Planmeca Viso	**Predicate device Planmeca ProMax 3D Max**
Intended use	Planmeca Viso is a system intended to produce two-dimensional (2D) and three-dimensional (3D) digital x-ray images as well as three-dimensional (3D) optical images of the dento-maxillo-facial, cervical spine and ENT (Ear, Nose, and Throat) regions at the direction of healthcare professionals as diagnostic support for pediatric and adult patients.	The Planmeca ProMax 3D Max or Maximity is a system intended produce two-dimensional (2D) and three-dimensional (3D) digital X-ray images of the dento-maxillo-facial, cervical spine and ENT (Ear, Nose and Throat) regions at the direction of healthcare professionals as diagnostic support for pediatric and adult patients.
3D Imaging		
Technical characteristics	• CBCT (cone beam computed tomography) • 300 - 600 projections over 210° / 360° rotation • Reconstruction time 30 s – 6 min • Voxel size 75-600µm	• CBCT (cone beam computed tomography) • 300 - 600 projections over 210° / 360° rotation • Reconstruction time 30 s – 6 min • Voxel size 75-600µm
Field Of View (FOV)	Ø30x30mm – Ø200x170mm (G5) / Ø300x300mm (G7)	Ø42x48mm - Ø230x260mm
2D Imaging		
Technology	• SmartPan panoramic imaging, tomosynthesis • Multiview panoramic imaging, tomosynthesis • Cephalostat	• SmartPan panoramic imaging, tomosynthesis • Multiview panoramic imaging, tomosynthesis • No cephalostat
Imaging system performance specifications		
X-ray detector	• Varex Imaging 16x16cm flat panel (G5) / 25x30cm flat panel detector (G7) • aSi with CsI scintillator • 127um pixel pitch (G5) / 139um pixel pitch (G7) • Bit depth 16bit • Varian PaxScan 2530C 30.2(w)x24.9(h)cm • GADOX scintillator	• Varex Imaging 25x20cm flat panel detector • aSi with CsI scintillator • 127um pixel pitch • Bit depth 15bit

X-ray tube and generator	• Fixed anode X-ray tube focal spot size 0.5 mm • Tube voltage 60-120 kV • Tube current 1-16 mA • Exposure time 0.1–36 sec (pulsed)	• Fixed anode X-ray tube with 0.6mm focal spot • Tube voltage 66-96 kV • Tube current 1-12,5 mA • Exposure time 3–24 sec (pulsed)
Other		
Workflow	• Open positioning, doctor facing the patient • Patient seated or standing	• Open positioning, doctor facing the patient • Patient seated or standing
Imaging Software	• Planmeca Romexis	• Planmeca Romexis

Cephalometric scanning feature and detector are identical to those in previously cleared reference devices. The PaxScan 2530C, used for cephalometric imaging in the subject device, was included as a cephalometric detector in a previously cleared 510(k) for the RAYSCAN α-Expert 3D (K142247).

VIII. PERFORMANCE DATA

Results from performance bench testing demonstrate that Planmeca Viso produces substantially equivalent image quality compared to the predicate and reference devices.

IX. CONCLUSIONS

The comparison of characteristics supports substantial equivalence. Planmeca Viso is as safe and effective as the predicate device.