



December 28, 2023

Planmeca Oy
Niina Vuorikallas
Director, Quality & Regulatory Affairs
Asentajankatu 6
Helsinki, 00880
Finland

Re: K230985
Trade/Device Name: Planmeca Viso
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: October 17, 2023
Received: November 3, 2023

Dear Niina Vuorikallas:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Gabriela M. Rodal Digitally signed by for
-S Gabriela M. Rodal -S

Lu Jiang, Ph.D.
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K230985

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER

Manufacturer

Planmeca Oy
Asentajankatu 6
00880 Helsinki, Finland
Phone: +358 20 7795 500
Fax: +358 20 7795 555
Contact person: Niina Vuorikallas

U.S. designated agent

Planmeca U.S.A. Inc.
2600 Forbs Ave.
Hoffman Est, IL 60192
UNITED STATES
Contact person: Glen Kendrick

Date Prepared: December 27, 2023

II. DEVICE

Name of Device:	Planmeca Viso
Common or Usual Name:	Computed Tomography X-ray System
Classification Name:	Computed Tomography X-ray System (CT) (21 CFR 892.1750)
Regulatory Class:	II
Product Code:	OAS

III. PREDICATE DEVICE

Primary predicate device, #1, Planmeca Viso, Computed Tomography System
510(k): K181576
Regulation number: 892.1750
Regulatory Class: II
Product Code: OAS

Predicate device #2, HDX DENTRI α , Computed Tomography System
510(k): K160140
Regulation number: 892.1750
Regulatory Class: II
Product Code: OAS

Predicate device #3, DigiX FDX, Stationary X-ray system
510(k): K223060
Regulation number: 892.1680
Regulatory Class: II
Product Code: KPR

Predicate device #2 is only used for X-ray tube comparison. Outside of figure 1, when referred to predicate device, the reference is made to primary predicate device, #1.

IV. 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 dedicated 3D reconstruction hardware) that can be viewed in three dimensions using separate workstation and Planmeca Romexis software.

V. INDICATIONS FOR USE

Same as predicate device.

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

General

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 for panoramic and cephalometric imaging. In general there are only a few changes in the device.

Integrated detector

The X-ray detectors used are of same size as previously. Viso G5 and ProCeph use new X-ray detectors with similar qualities as the predicate device. Only difference between Viso G7 predicate and subject devices is the interface. Predicate device uses proprietary interface, and subject device uses standard ethernet interface. This has some effects on the device hardware, namely the grabber PCB, which is being replaced with a commercial Nvidia Jetson Nano module and suitable interface PCB. Otherwise they are of similar qualities as before and the produced 3D images provide similar diagnostic value. See fig 2 for technical comparison between devices.

X-ray unit

The dimensions and materials are identical to the predicate device.

X-ray tube

A new x-ray tube has been introduced to the device. It is of similar quality as predicate devices' fixed anode x-ray tubes, and it has maximum tube voltage of 120kV. Previously used fixed anode x-ray tubes may also be used with this device. No other changes for the tube head. Predicate device #2 operates a similar tube manufactured by the same company, the only difference being the target angle and thus the heat characteristics. See fig 1 for technical comparison on X-ray tube properties.

fig 1. X-ray tube comparison

	Subject device	Primary predicate device, #1	Predicate device #2
Tube type	OPX/105-10	SXR 130-10-0.5 SC	OPX/105
Nominal voltage	120 kV	130 kV	110 kV
Focal spot	0.5 mm	0.5 mm	0.5mm
Filament characteristics	3.5 ÷ 6.0 V 2.5 ÷ 4.0 A	N/A	3.5 ÷ 6.0 V 2.5 ÷ 4.0 A
Anode material	Tungsten	Tungsten	Tungsten
Target angle	10°	10°	5°
Anode heat storage capacity	40000 J	31500 J	30000 J
Maximum anode cooling rate	500 W	310 W	250 W
Nominal anode input power at 0.1 s (DC)	1900 W	N/A	2000 W
Inherent filtration	0.5 mm Al	1.1 mm Al	0.5 mm Al

X-ray generator

The device uses the same x-ray generator as before.

X-ray collimator

The device uses the same x-ray collimator as before.

Software

Software changes made to accommodate new hardware (see integrated detectors and new x-ray tube).

CT reconstruction algorithm

Device uses same CT reconstruction algorithm as before, no significant changes are made to the algorithm.

fig 2. technical comparison		
Technical specification	Subject device	Primary predicate device, #1
Classification		
FDA product class	OAS, class II	OAS, class II
RoHS	2011/65/EU	2011/65/EU
IEC 60601-1	Class I, type B	Class I, type B
CISPR 11	Class B	Class B
IP Classification	IPX0	IPX0
Applied parts (according to IEC 60601-1: 2012)		
Patient supports	As shown in section Patient supports in user's manuals	As shown in section Patient supports in user's manuals
Patient handles		
Generator (according to IEC 60601-2-7: 1998)		

	Resonant-mode, DSP-controlled, 80 - 160 kHz	Resonant-mode, DSP-controlled, 80 - 160 kHz
X-ray tube		
	D-059SBR or SXR 130-10-0.5 SC or OPX 105-10	D-059SBR or SXR 130-10-0.5 SC
Focal spot size (according to IEC 60336: 2005)		
	0.5 x 0.5 mm	0.5 x 0.5 mm
Filtration		
3D	Total 2.5 mm Al + 0.2mm / 0.5 mm Cu	Total 2.5 mm Al + 0.2mm / 0.5 mm Cu
Pan (SmartPan) / ProCeph	Total 2.5 mm Al	Total 2.5 mm Al
Tube housing front cover quality equivalent filtration (not included in the specified total filtration)	0.3 mm Al @ 70 kV / HVL 2.6 mm Al	0.3 mm Al @ 70 kV / HVL 2.6 mm Al
Anode voltage		
3D	80 - 120 kV $\pm 5\%$	80 - 120 kV $\pm 5\%$
Pan (SmartPan)	60 - 84 kV $\pm 5\%$	60 - 84 kV $\pm 5\%$
ProCeph	60 - 84 kV $\pm 5\%$	60 - 84 kV $\pm 5\%$
Anode current		
3D	D-059SBR: 2-12.5 mA $\pm 10\%$ SXR 130-10-0.5 SC: 2-16mA $\pm 10\%$ OPX 105-10: 2-16mA $\pm 10\%$	D-059SBR: 1-12.5 mA $\pm 10\%$ SXR 130-10-0.5 SC: 1-16mA $\pm 10\%$
Pan (SmartPan)	D-059SBR: 2-14 mA $\pm 10\%$ SXR 130-10-0.5 SC: 2-16mA $\pm 10\%$ OPX 105-10: 2-16mA $\pm 10\%$	D-059SBR: 1-14 mA $\pm 10\%$ SXR 130-10-0.5 SC: 1-16mA $\pm 10\%$
ProCeph	D-059SBR: 14 mA $\pm 10\%$ SXR 130-10-0.5 SC: 16mA $\pm 10\%$ OPX 105-10: 14mA $\pm 10\%$	D-059SBR: 14 mA $\pm 10\%$ SXR 130-10-0.5 SC: 16mA $\pm 10\%$
mAs range		
	min. / max. as indicated $\pm(10\% +$ 0.2 mAs)	min. / max. as indicated $\pm(10\% +$ 0.2 mAs)
Dose range and accuracy		
	Dose range min. / max. as indicated on system user interface Accuracy of dosimetric indication (DAP, CTDI): $\pm 40\%$	Dose range min. / max. as indicated on system user interface Accuracy of dosimetric indication (DAP, CTDI): $\pm 40\%$

Linearity of radiation output		
	< 0.1	< 0.1
Exposure time		
3D	Pulsed, effective 1.5 - 36 s as indicated $\pm 10\%$	Pulsed, effective 1.5 - 36 s as indicated $\pm 10\%$
Pan (SmartPan)	2.5 – 15.6 s as indicated $\pm 10\%$	2.5 – 15.6 s as indicated $\pm 10\%$
ProCeph	0.1 - 1.6s as indicated $\pm 10\%$	0.1 - 1.6s as indicated $\pm 10\%$
SID		
3D / Pan (SmartPan)	700 mm	700 mm
Ceph	1700 mm (66.9 in.)	1700 mm (66.9 in.)
Magnification		
3D	1.40 - 1.71	1.40 - 1.71
Pan (SmartPan)	1.32	1.40
Ceph	1.13	1.13
Duty cycle for height adjustment		
	25 s ON / 400 s OFF	25 s ON / 400 s OFF
Line voltage		
	100 - 220 V \sim / 50 - 60 Hz 230 - 240 V \sim / 50 Hz	100 - 220 V \sim / 50 - 60 Hz 230 - 240 V \sim / 50 Hz
Line current		
	8 - 17 A	8 - 17 A
Input power		
Stand by	150 VA	150 VA
Exposure	1800 W	1800 W
Line harmonics		
	Cos better than 0.9	Cos better than 0.9
Max. permissible apparent impedance of supply mains		
	0.5 Ohms (100 VAC)	0.5 Ohms (100 VAC)
Max. continuous heat dissipation		
	250 W	250 W
Internal fuse(s)		

User replaceable - 1 fuse on permanently installed X-ray units	100 - 220 V~ / 16A FF H 500 V 230 - 240 V~ / 8A FF H 500 V	100 - 220 V~ / 16A FF H 500 V 230 - 240 V~ / 8A FF H 500 V
Type	195100 ELU	195100 ELU
External fuse(s)		
	100 - 220 V ~ / 16A min. - 20A max. T 250 V 230 - 240 V ~ / 10A min. - 20A max. T 250 V	100 - 220 V ~ / 16A min. - 20A max. T 250 V 230 - 240 V ~ / 10A min. - 20A max. T 250 V
Battery		
	Lithium battery: 3V, CR2032 Panasonic / Varta	Lithium battery: 3V, CR2032 Panasonic / Varta
Max. weight		
Base unit	165 kg (364 lb)	165 kg (364 lb)
ProCeph	20 kg (44 lb)	20 kg (44 lb)
Environmental requirements		
Transport:		
Temperature	-20°C - +60°C (-4°F - +140°F)	-20°C - +60°C (-4°F - +140°F)
Relative humidity	10 - 90% RH (non-condensing)	10 - 90% RH (non-condensing)
Air pressure	700 - 1060 hPa	700 - 1060 hPa
Storage:		
Temperature	-10°C - +50°C (+14°F - +122°F)	-10°C - +50°C (+14°F - +122°F)
Relative humidity	10 - 90% RH (non-condensing)	10 - 90% RH (non-condensing)
Air pressure	700 - 1060 hPa	700 - 1060 hPa
Operating:		
Temperature	+10°C - +30°C (+50°F - +86°F)	+10°C - +30°C (+50°F - +86°F)
Relative humidity	10 - 90% RH (non-condensing)	10 - 90% RH (non-condensing)
Air pressure	800 - 1060 hPa	800 - 1060 hPa
Max. altitude	2000 m (1.25 miles)	2000 m (1.25 miles)
Image properties		
ProCeph:		
Panel type	Varex 2530C Gen5	Varex 2530P
Flat panel pixel size	131 µm	139 µm
Flat panel active surface	302 x 249 mm (11.89 x 9.80 in.)	302 x 249 mm (11.89 x 9.80 in.)

DQE (0)	64 %	32 %
MTF	> 51 % @ 1lp/mm	> 48 % @ 1lp/mm
3D:		
Panel type	Viso G5: Varex 1616Z Viso G7: Varex 2530DX	Viso G5: Varex 1616PT Viso G7: Varex 2530PX
Flat panel pixel size	Viso G5: 105 µm Viso G7: 139 µm	Viso G5: 127 µm Viso G7: 139 µm
Flat panel active surface	Viso G5: 161.3 x 161.3 (6.35 x 6.35 in.) Viso G7: 247.7x 301.1 mm (9.75 x 11.85 in.)	Viso G5: 157.5 x 157.5 mm (6.20 x 6.20 in.) Viso G7: 299.7x 246.3 mm (11.80 x 9.70 in.)
DQE (0)	Viso G5: 78 % (1x1) Viso G7: 70 % (1x1)	Viso G5: 70 % (1x1) Viso G7: 70 % (1x1)
MTF	Viso G5: > 59 % @ 1lp/mm (1x1) Viso G7: > 48 % @ 1lp/mm (1x1)	Viso G5: > 48 % @ 1lp/mm (1x1) Viso G7: > 50 % @ 1lp/mm (1x1)
Voxel sizes	75 µm, 150 µm, 300 µm, 450 µm, 600 µm	75 µm, 150 µm, 300 µm, 450 µm, 600 µm
Pan (SmartPan):		
Panel type	Viso G5: Varex 1616Z Viso G7: Varex 2530DX	Viso G5: Varex 1616PT Viso G7: Varex 2530PX
Flat panel pixel size	Viso G5: 105 µm Viso G7: 139 µm	Viso G5: 127 µm Viso G7: 139 µm
Flat panel active surface	Viso G5: 8.4 x 161.3 mm (0.33 x 6.35 in.) Viso G7: 8.9/17.8 x 166.8 mm (0.35/0.7 x 6.57 in.)	8 - 25 x 146 mm (0.31 - 0.98 x 5.74 in.)
Operating requirements for ProFace program		
Optimum colour temperature	Approx. 6500 Kelvin	Approx. 6500 Kelvin
Even and uniform lighting		
No bright lights		

VII. PERFORMANCE DATA

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

Biocompatibility testing

No changes in patient contact parts compared to primary predicate device.

Electrical safety and electromagnetic compatibility (EMC)

CB and EMC testing was conducted as per IEC standards 60601-1+A1:2012+A2:2020, 60601-1-2+A1:2020, 60601-1-3+A1:2013+A2:2021, 60601-1-6+A1:2013+A2:2020, 60601-2-63+A1:2017+A2:2021, 62366-1+A1:2020 and 62304+A1:2015

Software Verification and Validation Testing

Software verification and validation was performed as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance of Premarket Submissions for Software Contained in Medical Devices.". No issues have been identified during the verification and validation process.

Bench testing

Performance testing in laboratory environment was performed with Viso (primary predicate device) and Viso (subject device) of the Sedentex and DIN 6868 Phantoms. The data was compared in order to see that the performance of the device remains substantially similar to that of the primary predicate device.

Clinical evaluation

The main measure of clinical performance for Planmeca Viso is determined to be image quality. This has been evaluated by the product relevant team of professionals who evaluated human phantom images which were determined to be suitable for the intended purpose and indications for use of the device. These results are substantially equivalent to the evaluation performed on primary predicate device.

AI Denoising feature of the endodontic image processing has been evaluated based on its ability to produce diagnostic image quality in its intended application. This was evaluated in a study performed by three dental professionals in a study conducted with eleven patients, by comparing images with no denoising and AI denoising.

Testing summary

The above testing confirms that Planmeca Viso is safe and effective in its intended use.

VIII. CONCLUSIONS

The performance data of the subject device and the predicate device is equal or close to equal. The performance testing provides data to back this similarity in the devices. The subject device performs equally or better in all the testing scenarios.

The IGZO technology is proven to bring improvements in electronic noise, image lag and noise-equivalent quanta. The IGZO technology has been used in several FDA approved devices at least since 2019.

The tube specifications regarding eg. focus size, anode angle and tube voltage are the same as previously approved Canon D-059SB X-ray tube. The OPX 105-10 X-ray tube is driven with the same hardware as our other previously approved X-ray tubes.

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