September 26, 2025

Planmed Oy
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
SAINT PAUL, MN 55114

Re: K250318
Trade/Device Name: Planmed XFI
Regulation Number: 21 CFR 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: SFV
Dated: August 26, 2025
Received: August 27, 2025

Dear Prithul Bom:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250318

Device Name

Planmed XFI

Indications for Use *(Describe)*

Planmed XFI is intended to be used for cone beam computed tomography imaging of anatomies within sections of the spine, of upper extremities including shoulder(s), hand, relative joints (shoulder (s), elbow, wrist) and of lower extremities including hip(s), foot and feet, and relative joints (hip(s), knee(s), ankle(s)).

The device is to be managed and operated/used in a professional healthcare environment by healthcare professionals and other legally qualified professionals only.

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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510(k) Summary (K250318)

I. SUBMITTER

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Date Prepared: September, 25th 2025

II. DEVICE

Name of Device:	Planmed XFI
Manufacturer	Planmed Oy
Common or Usual Name:	X-ray, computed tomography, cone-beam
Classification Name:	Computed Tomography X-ray System (CT) (21 CFR 892.1750)
Regulatory Class:	II
Product Code:	SFV
510(K) #	K250318

III. PREDICATE DEVICE

Name of Device:	NewTom 7G
Manufacturer	Cefla S.c,
Common or Usual Name:	System, X-ray, Tomography, Computed
Classification Name:	Computed Tomography X-ray System (CT) (21 CFR 892.1750)
Regulatory Class:	II
Product Code:	JAK
510(K) #	K220664

IV. DEVICE DESCRIPTION

The Planmed XFI X-ray unit utilizes cone beam computed tomography (CBCT) to generate three dimensional images. In CBCT imaging, a cylindrical volume of data is acquired in a single imaging procedure. This data comprises several hundred 2D images taken from various angles to encompass a specific pre-programmed target area. These images are subsequently employed for 3D reconstruction, accomplished through a dedicated PC equipped with reconstruction algorithms. The resulting reconstructed images can be visualized in three dimensions using a separate PC workstation equipped with suitable image viewer software.

V. INDICATIONS FOR USE

Similar as predicate device.

Planmed XFI is intended to be used for cone beam computed tomography imaging of anatomies within sections of the spine, of upper extremities including shoulder(s), hand, relative joints (shoulder(s), elbow, wrist) and of lower extremities including hip(s), foot and feet, and relative joints (hip(s), knee(s), ankle(s)).

The device is to be managed and operated/used in a professional healthcare environment by healthcare professionals and other legally qualified professionals only.

Characteristic	Proposed Device	Predicate Device	Variance Explanation
Device name	Planmed XFI	NewTom 7G	
Manufacturer	Planmed Oy	Cefla S.c	
510(k) number	K250318	K220664	
Figure			
Regulation number	21 CFR 892.1750	21 CFR 892.1750	No difference
Regulation description	Computed Tomography X-ray system	Computed Tomography X-ray system	No difference
Device Class	2	2	No Difference
Classification Product Code	SFV (classification Product Code)	JAK (classification Product Code) OAS (Subsequent product code)	Similar with exception: ENT and maxillofacial anatomies not included in XFI Intended use. OAS not included in XFI
Indication for use	Planmed XFI is intended to be used for cone beam computed tomography imaging of anatomies within sections of the spine, of upper extremities including shoulder(s), hand, relative joints (shoulder(s), elbow, wrist) and of lower extremities including hip(s), foot and	The device NewTom 7G is a cone beam computed tomography X-ray system. It is intended for diagnostic use obtaining geometric information and radiologic density from two-dimensional and three-dimensional images of anatomic particulars and objects in the examined area.	Similar with exception: ENT and maxillofacial anatomies not included in XFI Intended use.

	feet, and relative joints (hip(s), knee(s), ankle(s)). The device is to be managed and operated/used in a professional healthcare environment by healthcare professionals and other legally qualified professionals only.	The NewTom 7G is a computerized tomographic system using the cone-beam technology which acquires a sequence of images of the head, including ear, nose and throat (ENT), of dental and maxillofacial unit, teeth, mandible and jaw, of the temporomandibular joint (TMJ), human cranium and neck with sections of the cervical rachis, sections of the spine, of the upper limbs, including the shoulder, and the of lower limbs, including the hip, for diagnostic use. The device carries out such operations by reconstructing a 3D matrix of the examined volume and producing two-dimensional views of the volume and then displaying two- and three-dimensional images. The device is managed and used by doctors, dentists, radiologists, and other legally qualified professionals.	

Anatomical Parts	• Section of Spine • Upper and lower extremities, Including Hips and Shoulders	• Maxillofacial • Dental • Ear-Nose-Throat • Temporomandibular Joint • Human Skull • Section of Spine • Upper and lower extremities, Including Hips and Shoulders	Similar with exception: ENT and maxillofacial anatomies not included in XFI Intended use.
Principle of operation	Cone Beam Computed Tomography x-ray	Cone Beam Computed Tomography x-ray	No difference
Patient population	Adult, Pediatric	Adult, Pediatric	No Difference
Scan Axis	Horizontal and Vertical	Horizontal	The predicate device cannot be used in weight bearing mode. With vertical scan.
Sampling angle	360°	360°	No difference
Typical Resolution	75 – 600 µm	90 – 500µm	No significant differences in voxel size.

Scan Time	8 – 40 seconds Minimum Scan time: Protocol, Chest [S] 8 Second scan Low mode 400 frames 100kV, 180mAs @ 50 fps Normal Scan time: Protocol, Knee [M] 21 second scan Normal mode 500 frames 100kV, 160mAs @ 24 fps Maximum scan time: Protocol, Pelvis [L] 40 second scan HD mode 600 frames 140kV, 800mAs @ 15 fps	7.2 - 26 seconds	Scan times can vary on regarding the detector frame rate and imaging protocol Scan times are roughly the same between the scanners In extreme cases, the Planmed XFI has the capability to do longer exposures to ensure the image quality (e.g. Obese patients) in respect of allowed x-ray source loading factors.
Exposure time	2.8 – 13.1 seconds Minimum exposure time: 2.8 seconds Extremities [S] Low mode 400 frames 80kV,22mAs @ 24 fps @ 8mA tube current Normal exposure time: 3.6 seconds Extremities/Torso [M] Normal mode 500 frames 100kV, 160mAs @ 24 fps @ 45mA tube current Maximum exposure time: 13.1 seconds Pelvis [L] HD mode 600 frames 140kV, 800mAs @ 15 fps @ 61mA tube current	1.4 – 8.8 seconds	Approx. same exposure time and current time product with predicate device Exposure times are roughly the same between the scanners In extreme cases, the Planmed XFI has the capability to do longer exposures to ensure the image quality (e.g. Obese patients) in respect of allowed x-ray source loading factor.

SID	1080 mm	980 mm	No significant difference with SID
Automatic exposure correction (AEC)	✓	✓	No differences
Viewing and reconstruction software	Romexis FDK	NNT FDK	Same reconstruction algorithm with predicate device
Software validation	IEC 62304 + Guidance FDA on MD SW	IEC 62304 + Guidance FDA on MD SW	No difference
Patient positioning guides	Lasers and Scout images	Lasers and Scout images	No difference
Iso centric Imaging	✓	✓	No difference
Non-isocentric imaging	✓	--	Planmed XFI has offset imaging capability for increased FOV size
3D imaging mode	✓	✓	No difference
3D imaging volume (Field of View)	5 x 5 cm to 44 x 21 cm	4 x 4 cm to 17 x 32 cm	The proposed device utilizes a larger detector element 43 x 43 vs. 30 x 30 Enabling larger FOV

Line voltage	200-240 V ~ 50-60 Hz 16-20A	230 V ~ 50-60 Hz 16A	The proposed device accepts wider input voltage range.
Electrical safety	Complies with IEC6060-1:2012	IEC6060-1:2012	No difference
Electromagnetic compatibility	Complies IEC 60601-1-2:2014	Complies IEC 60601-1-2:2014	No difference
High Voltage Power supply	High frequency generator	High frequency generator	No difference
X-ray condition	Pulsed	Pulsed	No difference
X-ray tube Power Rating [kW] and technique factor	max 14 kW @ 140 kV, 100mA	max 14.4 kW @ 120 kV, 120 mA	No significant difference with X-ray tube power with predicate
Anode	Rotating (10 000rpm)	Rotating (10 000 rpm)	No difference
X-ray tube	IAE, RTM 782 HS or VAREX, RAD 14 mod	IAE, RTM 70 H	No significant difference with X-ray tube with predicate device.
Anode angle	12.5 degrees	10 degrees	XFI has a slightly wider anode angle to cover larger detector area than Newtom 7G with given SID

Anode Heat content	225 kJ	225 kJ	No difference
Max continuous heat dissipation	750 W	750 W	No difference
Tube Voltage range [kV]	80 – 140 kV	70 – 120 kV	No significant difference with tube voltage
Tube Current range [mA]	5 – 100 mA	5 – 120 mA	No significant difference with mA range
Focal spot	0.3 / 0.6 mm	0.3 / 0.6 mm	No difference
Collimation	Adjustable, Squared	Adjustable, Squared	No difference
Filtration	Total 2.5 mm Al (permanent) + 0.2/0.5/1.0 mmCu Bowtie CuZn 0.2-2mm option	Total 21 mm Al eq. @ 70 kV	Filtration is adjusted regarding desired x-ray beam spectrum and to optimize low dose imaging.
Image Detector	Amorphous Silicon flat panel (CsI)	Amorphous Silicon flat panel (CsI)	No difference
Active detector area	43 x 43 cm	30 x 30 cm	Larger detector size enables larger field-of-view.

Pixel size	147 µm	154 µm	No significant difference with pixel size. Smaller pixel size should create more detailed images in theory.
Gray Scale	16 bit	16 bit	No difference
Image transfer	Ethernet and fibre optical cable	Ethernet cable	Optical cable for faster data transfer in proposed device
Image format	DICOM	DICOM	No difference
Weight	550 kg	1050 kg	Weight Is lower with the proposed device.
Bore size	85cm, circular	77cm, circular	Larger bore size compared to predicate device
Maximum dimensions	H:1755 mm W: 1620 mm L: 2475 mm	H: 2083 mm W: 2057mm L: 3938 mm	The proposed device requires a smaller footprint for the installation
Movements	Gantry rotation and 3 motorized axes (x,y,z) x-ray source and detector linear movement	Gantry rotation and 3 motorized axes (x,y,z)	Detector and x-ray source movement allows larger field of view for proposed device
Installation	Horizontal, floor or Vertical, Wall mounted (weight bearing)	Horizontal, Floor	The proposed device can be mounted into the wall, enabling weight bearing imaging of the patient
Operating temperature	+20 - +30 °C	+10 - +35 °C	No significant difference with given operating temperature range

Operating humidity condition	10-90 % RH (non-condensing)	10- 85% RH (non-condensing)	No significant difference with given humidity conditions
Pressure	800-1060hPA	710-1060hPa	No significant difference with given pressure conditions

VI. PERFORMANCE DATA

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

Biocompatibility testing

The subject device is intended for use on intact skin for limited duration of less than 24 hours. Therefore risk based assessment of the biological safety was performed, following the guidelines presented in *"Attachment G: Biocompatibility of Certain Devices in Contact with Intact Skin"* of FDA guidance document *"Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, September 2023"*, with additional consideration given to ISO 10993-1:2018 standard which similarly notes that testing is not usually necessary when sufficient information is already available to perform a risk assessment on the material and the medical device.

Risk assessment of biological characteristics of the subject device was performed to provide evidence of the prospective and risk-based biological planning process and conclude on the biological testing strategy applicable for the device. This biological risk assessment of the subject device is based on the intended use of the medical device, its biocompatibility, and manufacturing process (including packaging and sterilization).

Electrical safety and electromagnetic compatibility (EMC)

The Planmed XFI CBCT device was evaluated for compliance with internationally recognized medical safety and performance standards. Testing included assessments of electrical safety, mechanical safety, thermal safety, electromagnetic compatibility (EMC), and laser safety.

Electrical Safety: Tested according to IEC 60601-1 with amendments A1:2012 and A2:2020, confirming safe levels of leakage current, insulation, grounding, and operating parameters.

Mechanical Safety: Evaluated under IEC 60601-1, with amendments A1:2012 and A2:2020, confirming resistance to impact, enclosure integrity, and safe operation of moving parts.

Thermal Safety: Assessed under IEC 60601-1, with amendments A1:2012 and A2:2020, verifying safe surface temperatures during use and effective protection against overheating.

Electromagnetic Compatibility (EMC): Tested according to IEC 60601-1-2, with amendment A1:2020, demonstrating that the device does not cause harmful interference and operates reliably in the presence of electromagnetic disturbances.

Laser Safety: Tested according to IEC 60825-1:2014, confirming correct classification, safe emission levels, and appropriate labeling and protective measures.

Software Design & Verification

Device software was designed, developed and tested in accordance with IEC 62304:2015. Software hazard analysis including mitigations was performed according to ISO 14971:2019

standard. Additionally, FDA guidance "*Content of Premarket Submissions for Device Software Functions, Guidance for Industry and Food and Drug Administration Staff, June 2023*" was used as guidance for software design and documentation on Basic Documentation Level.

Tests for entire software system were completed on unit and system level including verification of risk mitigations to ensure that software system is as safe and effective as the predicate. Tests were traced to user and design requirements.

Cybersecurity requirements and documentation set by FDA guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, Guidance for Industry and Food and Drug Administration Staff, June 2025" for pre-submission and post market cybersecurity follow up was used as guideline for activities to be performed in said phases to ensure that device remains as safe and effective as the predicate during the total lifecycle of the device. Additionally, IEC 85001-5-1:2021 was used as standard for secure software design and development.

Software Validation

Usability testing according to IEC 60601-1-6, with amendments A1:2013 and A2:2020, was conducted in order to confirm that user interactions can be performed safely and effectively regarding to users & use environment XFI-device is intended to be used.

(Pre-)Clinical image evaluation

Performance testing consisted of bench testing, phantom imaging and cadaver imaging.

The bench testing was performed using an image quality phantom. We measured HU-value accuracy, contrast-to-noise ratio, image uniformity, image homogeneity, modular transfer function (resolution), geometric distortion, and slice thickness with varying FOV and matching doses against the predicate device. All the testing showed similar or better performance of Planmed XFI over the predicate device.

The image quality phantom testing was completed as an extensive head-to-head comparison between the Planmed XFI and the predicate device with anthropomorphic phantoms: the same phantoms were scanned with the same radiation dose in multiple different image resolutions. All anatomies of the intended use were covered in the assessment. In total, five different radiologists assessed the phantom image quality in a blinded study. All the testing showed the same performance between Planmed XFI and the predicate device.

The phantom evaluation was supplemented with a cadaver study, where all anatomies of the intended use were covered, which demonstrated that the imaging performance of the Planmed XFI was of a diagnostic and clinically acceptable level. These images were evaluated by three US board certified radiologists.

In bench testing and head-to-head phantom study comparison with the predicate device, the image quality was essentially the same. The new CBCT scanner Planmed XFI has demonstrated diagnostically and clinically sufficient image quality also in cadaver studies of

the anatomies. The results of the image quality review have demonstrated that the device is substantially equivalent to the predicate device.

VII. CONCLUSIONS

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