May 6, 2022

Cefla S.c.
℅ Lorenzo Bortolotti
Managing Director
Via Selice Prov.le 23/
Imola, Bologna 40026
ITALY

Re: K220664
Trade/Device Name: NewTom 7G
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK, OAS
Dated: March 2, 2022
Received: March 17, 2022

Dear Lorenzo Bortolotti:

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).

Sincerely,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT 8B: Division of Radiological Imaging
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220664

Device Name
NewTom 7G

Indications for Use *(Describe)*
The NewTom 7G is a computed tomography x-ray imaging system using the cone-beam technology which acquires sequences of images of the head, including ear, nose and throat (ENT), of the dento-maxillofacial complex, teeth, mandible, jaw and temporomandibular joint (TMJ), of the other areas of the human skull and neck with sections of upper cervical spine, of the spine sections, of upper extremities including shoulder, upper arm, forearm, hand, relative joints and of lower extremities including hip, upper leg, lower leg, midfoot, forefoot, relative joints, for use in diagnostic support.
The device accomplishes this task by reconstructing a 3D matrix of the examined volume and producing two-dimensional views of this volume, displaying both two and three dimensional images.
The device is managed and used by doctors, dentists, radiologists and other legally qualified professionals.

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
PRAStaff@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 AS REQUIRED BY 21 CFR 807.92

Submitter's Name:	CEFLA S.C.
Address:	Via Selice Provinciale 23/a Imola, BO 40026 ITALY Tel. +39 0542 653111 Fax +39 0542 653444
Establishment Registration No. :	3006610845
Contact Person:	Lorenzo Bortolotti, Regulatory Affairs
Telephone Number:	+39 0542 653441
Email Address:	regulatory@cefla.it
Date prepared:	March 02nd, 2022

Device name:	NewTom 7G
Device:	System, X-Ray, Tomography, Computed
Regulatory description:	Computed tomography X-ray system
Regulation Number:	21 CFR §892.1750
Device Class:	2
Classification Product Code:	JAK
Subsequent Product Code:	OAS

Device Description:

NewTom 7G is a computed tomography X-ray system using the cone-beam technology manufactured by CEFLA S.C. The proposed device NewTom 7G is a further development of the predicate device NewTom 5G XL (K183448) manufactured by CEFLA S.C.

Like the predicate device NewTom 5G XL the proposed device NewTom 7G is equipped with X-ray tube generator and X-ray sensor (solid state X-ray imaging detector) for radiological images acquisition.

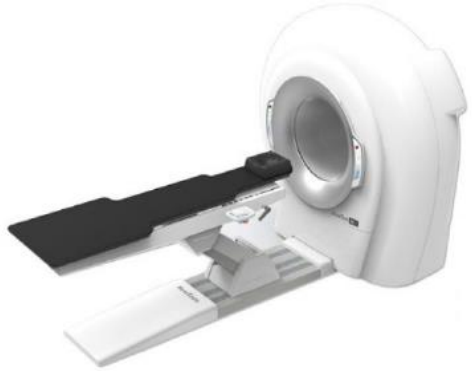
The proposed device permits to acquire radiological images at varying radiographic angles by rotating around the patient. The exposed area can be adapted to a specific region of interest to keep the radiation dose as low as possible. This is achieved by collimating the X-ray beam. Furthermore, the radiation dose can be adapted by various parameters such as examination types and exposure technique factors. Class I lasers pointers are utilized to aid the patient positioning. The patient stay lie down on the patient support for a good stabilization. Control panel allow user actions as: patient support adjustment, selection of examination, selection of exposure parameters and delivers information about the unit status. The obtained digital image data are processed to provide a reconstructed image. The images are transferred to a computer. The software used to manage the images is NNT, a radiological imaging software developed by CEFLA S.C.

Indication for Use:	NewTom 7G is a computed tomography X-ray imaging system using the cone-beam technology which acquires sequences of images of the head, including ear, nose and throat (ENT), of the dento-maxillofacial complex, teeth, mandible, jaw and temporomandibular joint (TMJ), of the other areas of the human skull and neck with sections of upper cervical spine, of the spine sections, of upper extremities including shoulder, upper arm, forearm, hand, relative joints and of lower extremities including hip, upper leg, lower leg, midfoot, forefoot, relative joints, for use in diagnostic support. The device accomplishes this task by reconstructing a 3D matrix of the examined volume and producing two-dimensional views of this volume, displaying both two- and three-dimensional images. The device is managed and used by doctors, dentists, radiologists and other legally qualified professionals.
Identification of Predicate Device	The **predicate device** identified relating the substantial equivalence of the proposed device is: Device Name: NewTom 5G XL 510(k) Number: K183448 Device: System, X-Ray, Tomography, Computed Regulation Description: Computed tomography x-ray system Applicant: CEFLA S.C. Via Selice Provinciale 23/A Imola, IT 40026 Regulation Number: 21 CFR §892.1750 Device Class: Class II Classification Product Code: JAK Subsequent Product Code: OAS

Substantial Equivalence

NewTom 7G is a further development of the predicate device NewTom 5G XL (K183448). The devices have the same intended use, same clinical conditions, the same target population and the same operating principles. Both devices have similar design and meet the same requirements from technical standards. The NewTom 7G technology has no innovative aspects compared to the predicate device NewTom 5G XL, but represents an incremental development of technical performances and usability.
The aim of these improvements is giving to the professionals a tool to better answer the diagnostic questions. The improvements are based on the client's feedback and on more than twenty years' experience in R&D, production and world-wide distribution of CBCT devices.

The following cross reference table shows similarity and diversity aspects between the proposed device and the predicate device:

Characteristic	**Proposed Device**	**Predicate Device**	**Differences discussion**
Device Name	**NewTom 7G**	**NewTom 5G XL**	
Manufacturer	**CEFLA S.C.**	**CEFLA S.C.**	
510(K) No.	**-**	**K183448**	
Figure			Equivalent shape: toroidal gantry with patient bed.
Classification			
Regulation Number	892.1750	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	JAK (Classification Product Code) OAS (Subsequent Product code)	JAK (Classification Product Code) OAS (Subsequent Product code)	No difference.
Acquisition technique	X-ray cone beam computed tomography	X-ray cone beam computed tomography	No difference.
Indication for use			
Indication for use	The NewTom 7G is a computed tomography X-ray imaging system using the cone-beam technology which acquires sequences of images of the head, including ear, nose and throat (ENT), of the dento-maxillofacial complex, teeth, mandible, jaw and temporomandibular joint (TMJ), of the other areas of the human skull and neck with sections of upper cervical spine, of the spine sections, of upper extremities including shoulder, upper arm, forearm, hand, relative joints and of lower extremities including hip, upper leg, lower leg, midfoot, forefoot, relative joints, for use in diagnostic support. The device accomplishes this task by reconstructing a 3D matrix of the examined volume and producing two-dimensional views of this volume, displaying both two- and three-dimensional images. The device is managed and used by doctors, dentists, radiologists and other legally qualified professionals.	The NewTom 5G XL is cone-beam computed tomography X-ray imaging system that acquires sequences of images of the head, including ear, nose and throat (ENT), of dento-maxillofacial complex, teeth, mandible and jaw, temporo-mandibular joint (TMJ), other areas of the human skull and neck with sections of upper cervical spine and of the upper and lower extremities for use in diagnostic support. The device accomplishes this task by reconstructing a 3D matrix of the examined volume and producing two-dimensional views of this volume, displaying both two- and three-dimensional images. The device is operated and used by physicians, dentists, X-ray technologists and other legally qualified professionals.	Indications for use are equivalent. The anatomical elements have been better listed in the indications for use of the NewTom 7G.

Anatomical parts	Maxillofacial Dental Ear-Nose-Throat (ENT) Temporomandibular Joint (TMJ) Human skull Neck Section of spine Upper and lower extremities	Maxillofacial Dental Ear-Nose-Throat (ENT) Temporomandibular Joint (TMJ) Human skull Neck Section of spine Upper and lower extremities	No significant difference. The NewTom 7G allows to visualized sections of the whole spine. It is due by increased radiological parameters: kV, mA available and bigger gantry opening size.
Performance features			
Patient population	Adult, Pediatric	Adult, Pediatric	No difference.
Minimum patient size	Particularly designed for use with patients more than 11 kg (24 lb) in weight and more than 87 cm (34.25”) in eight; these height and weight measurements approximately correspond to that of an average 3-year-old child.	Particularly designed for use with patients more than 11 kg (24 lb) in weight and more than 87 cm (34.25”) in eight; these height and weight measurements approximately correspond to that of an average 3-year-old child.	No difference.
Selectable parameters	Anatomical position, scan protocol types, Field of View (FOV)	Anatomical position, scan protocol types, Field of View (FOV)	No difference.
Scan modes	LOW DOSE SCAN REGULAR SCAN ENHANCED SCAN BEST SCAN	ECO SCAN REGULAR SCAN ENHANCED SCAN	An additional scans mode “BEST SCAN” has been added due to extended range of radiological parameters available with NewTom 7G. For children LOW DOSE SCAN is recommended like ECO SCAN is recommended with the predicate device NewTom 5G XL (K183448).
Technical & Functional features comparison: Rated input			

Rated input	16A @ 230 V~ 50/60 Hz	20A @ 115V~ 12A @ 240V~ 50/60 Hz	Increased available X-ray load factors with proposed device required more input power. However electromagnetic compatibility and electrical safety of both proposed and predicate devices have found in compliance with consensus standard IEC 60601-1 and particular and collateral applicable standards.
Technical & Functional features comparison: X-ray emission			
Type of X-ray emission	Pulsed	Pulsed	No difference.
Anode material	RTM	RTM	No difference.
Nominal tube voltage	130 kV	120 kV	The X-ray tube assembly of NewTom 7G is designed to manage higher X-ray loading factors than NewTom 5G XL (K183448).
Rotating anode speed	10.000 rpm	10.000 rpm	No difference.
Focal spot (IEC 60336)	0.3 / 0.6 mm	0.3 / 0.6 mm	No difference.
Max used tube voltage	120 kV	110 kV	The increase in the maximum available kV compensates the increased dimensions, increased beam filtration and gives the possibility to select higher X-ray load factors especially with high density parts or big-size patients.

Max continuous heat dissipation	750 W	300 W	The X-ray tube assembly of NewTom 7G is designed to manage higher X-ray loading factors than NewTom 5G XL (K183448).
Anode angle	10°	15°	No significant difference. It depends to NewTom 7G geometry.
Type of collimator	Motorized variable collimator	Motorized variable collimator	No difference.
Shape of X-ray beam	CBCT (Cone Beam) SQUARED	CBCT (Cone Beam) SQUARED	No difference.
Total filtration	21 mm Al eq. @ 70kV	11.2 mm Al eq. @ 70kV	The increased total filtration of NewTom 7G compared to NewTom 5G XL (K183448) allows to obtain a better X-ray beam quality reducing useless dose contribution of low-energy X-ray beam.
Typical Range CDTIw (mGy) measured according IEC 60601-2-44	17,61 [15x6] Best Quality - 1,23 [17x12] Low Dose	24,2 [15x5] HiRes, Enhanced - 1,5 [8x8] Eco	The typical CDTIw values obtained with NewTom 7G are comparable or lower than the typical CTDIw values measured with the NewTom 5G XL (K183448).
Additional fixed acquisition	Ray2D (it allows acquiring a single X-ray image saved on an image file), CineX / CineScout (it allows for the dynamic acquisition of a set sequence of X-ray images saved on a video)	Ray2D (it allows acquiring a single X-ray image saved on an image file), CineX (it allows for the dynamic acquisition of a set sequence of X-ray images saved on a video)	No difference.
Technical & Functional features comparison: SSD X-ray sensor & IMAGE Acquisition			

Detector technology	Amorphous Silicon flat panel X-ray detector	Amorphous Silicon flat panel X-ray detector	No difference.
Detector dimensions	300 mm x 300 mm	260 mm x 300 mm	The size of active area on the Solid State Detector available with proposed device is greater than the one available with the predicate device. This fact combined with the slightly bigger geometry of the NewTom 7G allows to achieve larger FOVs than those available with the NewTom 5G XL (K183448).
Image detector conversion screen (scintillator material)	CsI	CsI	No difference.
Detector pixels	1956x1956 pixels	1560x1440 pixels	A higher pixels number of the SDD's matrix depends from the size of active area and the pixel size.
Detector pixel size	154 µm	184 µm	The size of the pixel of the Solid State Detector available with proposed device is smaller than the one available with the NewTom 5G XL (K183448). Smaller pixel size potentially allows to obtain an higher image resolution.
Quantization depth	16 bits	16 bits	No difference.
Communication / image transfer	Ethernet cable	Ethernet cable	No difference.

Reconstruction Voxel sizes min-MAX	90 ÷ 600 µm (available voxels depend from the FOV and scan mode)	100 ÷ 300 µm (available voxels depend from the FOV and scan mode)	The NewTom 7G allows to obtain reconstructed volume data with a minimum voxel size of 90µm (high resolution images) instead with the predicate device NewTom 5G XL (K183448) the minimum voxel size achievable is 100µm.
Gantry Aperture size	770 mm	580 mm	Bigger gantry aperture size allows an easier patient positiong and increases the patient confort.
Minimum focal spot to skin distance (source-object)	200 mm	150 mm	The NewTom 7G focal spot to skin distance is greater than NewTom 5G XL (K183448). Both values are according to the requirements of the recognized consensus standard IEC 60601-2-44.
Sampling angle or 3D's total view angle	360°	360°	No difference.
Technical & Functional features comparison: Laser & positioning			
Number of laser pointer	2 lasers volumetric pointers	2 lasers volumetric pointers	No difference.
Laser optical class	Class 1 for IEC 60825-1	Class 1 for IEC 60825-1	No difference.
Patient position	Lie on the bed	Lie on the bed	No difference.
Patient bed	3 motorized axes (x,y,z)	3 motorized axes (x,y,z)	No difference.
Technical & Functional features comparison: Control & Viewing Software			

Viewing & Reconstruction software	NNT	NNT	The software has been updated to include the management of NewTom 7G. Changes have been managed according to the recognized consensus standard IEC 62304 and the FDA Guidance on Medical Device Software.
Software validation	IEC 62304 + Guidance FDA on MD SW	IEC 62304 + Guidance FDA on MD SW	No difference.
Electrical Safety & Electromagnetic compatibility			
Electrical safety	Complies with IEC 60601-1: 2012	Complies with IEC 60601-1:2012	No difference.
Electromagnetic compatibility	Complies IEC 60601-1-2:2014	Complies IEC 60601-1-2:2014	No difference.

Non-clinical Performance Testing:

Testing to verify the performance requirements of the proposed device was conducted and included in this premarket notification. The results of the performance testing support substantial equivalence.

Tests included in this premarket notification verify the conformity of the proposed device with the requirements of:

- IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (including US National Differences).
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- IEC 60601-1-3: Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment.
- IEC 60601-1-6: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability.
- IEC 60601-2-28: Medical electrical equipment - Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis.
- IEC 60601-2-44: Medical electrical equipment - Part 2: Particular requirements for the safety of X-ray equipment for computed tomography.
- IEC 60825-1: Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 62304: Medical device software - Software lifecycle processes.
- Verification activities for confirmation of the image quality of the proposed device has been performed. The results of the image quality review have demonstrated that the device is substantially equivalent to the predicate device.

Clinical Testing

Given the differences from the predicate device, no human clinical studies have been considered necessary to support substantial equivalence.

Conclusion

The information included in this premarket notification supports the substantial equivalence of the proposed device NewTom 7G. The proposed device is an incremental development of the Cefla's own legally marketed predicate device: NewTom 5G XL (K183448). The proposed device has identical intended

use and fundamental principles of operation. The proposed device showed comparable basic safety and essential performances as the legally marketed predicate device. Differences between the devices shown in the comparison section above do not reasonably involves in negative effects on substantial equivalence.