December 14, 2023

Dentium Co., Ltd (ICT Branch)
% Dave Kim
Medical Regulatory Affairs
Mtech Group
7505 Fannin St. Suite 610
HOUSTON, TX 77054

Re: K231181
Trade/Device Name: bright CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: April 20, 2023
Received: April 26, 2023

Dear Dave Kim:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
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

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)*
K231181

Device Name
bright CT

Indications for Use *(Describe)*

bright CT is a computed tomography x-ray system intended to produce 3D, panoramic, and cephalometric diagnostic images of the maxillofacial areas for treatment planning for adult and pediatric patients. The device is operated and used by physicians, dentists, and x-ray technicians.

Rainbow 3D Image Viewer software features functions for acquiring, saving, searching, displaying, diagnosing and sending digital X-ray image data in dental practices and clinics.

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.

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510(k) Summary
K231181

This 510(k) is being submitted in accordance with the requirements of 21 CFR §807.92.

1. Date Summary Prepared: November 15, 2023

2. Submitter's Identification:

Submitter's Name :	Dentium Co., Ltd (ICT Branch)
Submitter's Address:	76, Changnyong-daero 256beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16229 Republic of Korea
Submitter's Telephone:	++82-70-7098-6932
Contact person:	Mr. Sang Woo Lee (swlee1@dentium.com)
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(U.S. Designated agent)	Mtech Group
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Telephone:	+1- 713-467-2607
Email:	davekim@mtechgroupllc.com

3. Device:

Trade /Proprietary Name:	bright CT
Device Classification Name:	X-Ray, Tomography, Computed, Dental
Regulation Description:	Computed tomography x-ray system.
Regulation Medical Specialty:	Radiology
Review Panel:	Radiology
Product Code:	OAS
Regulation Number:	21 CFR 892.1750
Device Class	2

4. Predicate Device:

Legally Marketed Predicate Device Information:

510(k) Number:	K200271
Trade /Proprietary Name:	rainbow CT
Device Classification Name:	X-Ray, Tomography, Computed, Dental
Regulation Description:	Computed tomography x-ray system.
Review Panel	Radiology
Product Code	OAS
Regulation Number	21 CFR 892.1750
Device Class	2

5. Device Description:

bright CT is a cone beam CT X-ray device for generating sectional images of dental images such as tooth, nasal cavity and temporomandibular joint. this is a medical diagnostic equipment designed to generate sectional images by placing X-ray source opposite to the imaging detector unit and rotating it around a patient. 2D images of the region of interest are reconstructed using a mathematical algorithm in 3 dimensional volumetric view and displayed on the computer monitor.

The system is composed of X-ray generator, X-ray detector, X-ray collimator, main frame, rotation unit, PC and Monitor, etc. in compliance with US performance standard and regulatory requirement.

6. Indications for use:

bright CT is a computed tomography x-ray system intended to produce 3D, panoramic, and cephalometric diagnostic images of the maxillofacial areas for treatment planning for adult and pediatric patients. The device is operated and used by physicians, dentists, and x-ray technicians.

Rainbow 3D Image Viewer software features functions for acquiring, saving, searching, displaying, diagnosing and sending digital X-ray image data in dental practices and clinics.

7. Summary of the technological characteristics of the device compared to the predicate devices:

Summary of the Technological Characteristics

Descriptive Information		bright CT Dentium Co., Ltd (ICT Branch)		rainbow CT (K200271) Dentium Co., Ltd (ICT Branch)
Indications for Use		brightCT is a computed tomography x-ray system intended to produce 3D, panoramic, and cephalometric diagnostic images of the maxillofacial areas for treatment planning for adult and pediatric patients. The device is operated and used by physicians, dentists, and x-ray technicians. Rainbow 3D Image Viewer software features functions for acquiring, saving, searching, displaying, diagnosing and sending digital X-ray image data in dental practices and clinics.		rainbow CT is a computed tomography x-ray system intended to produce 3D, panoramic, and cephalometric diagnostic images of the maxillofacial areas for treatment planning for adult and pediatric patients. The device is operated and used by physicians, dentists, and x-ray technicians. Rainbow 3D Image Viewer software features functions for acquiring, saving, searching, displaying, diagnosing and sending digital X-ray image data in dental practices and clinics.
Image Acquisition Modes		Panoramic, cephalometric and computed tomography		Panoramic, cephalometric and computed tomography
Imaging Software		Rainbow 3D ImageViewer		Rainbow 3D ImageViewer
Input Voltage		AC 100-230V, 50/60 Hz		AC 100-240 V, 50/60 Hz
Tube Voltage		60~100kV		60~100 kV
Tube Current		4~12 mA		4~12 mA
Focal Spot Size		0.5 mm		0.5 mm
Exposure Time		Max. 20 s For Stitching: Max. 40S		Max. 19 s
Slice Width		0.1 mm min.		0.1 mm min.
Total Filtration		3 mm Al		2.8 mm Al
Chin Rest		Bite block, chin rest and headrest		Bite block, chin rest and headrest
Mechanical		Compact design		Compact design
Electrical		LDCP logic circuit (Low Dark Current Processing)		LDCP logic circuit (Low Dark Current Processing)
Software		Rainbow 3D ImageViewer, DICOM 3.0 Format compatible		Rainbow 3D ImageViewer, DICOM 3.0 Format compatible
Anatomical Sites		Maxillofacial		Maxillofacial
Image	**CBCT**	DTX1512	DTX1524	C12820DK-40

Receptor Note: CT and panoramic image performance is identical because the sensors are identical.	**Panoramic**	DTX1512	DTX1524	C12820DK-40
	MTF@ 1 lp/mm	54%	53%	53%
	DQE @ 0.5 lp/mm	88%	85%	85%
	Image Size (cm)	14.5 x 11	14.5 x 22.5	Max. 10x8.5
	Cephalometric	DTX2906		C10502D-43
	MTF@ 1 lp/mm	53%		56%
	DQE @0.5 lp/mm	80%		60%
	Image Size (cm)	26.6 x 29 cm		22 x 0.6 cm
Pixel Resolution	**CBCT**	2 lp/mm – 1-4 subsampling	2 lp/mm – 1-4 subsampling	2 lp/mm – 2x2 binning
	Panoramic	4 lp/mm – 1x1	4 lp/mm – 1x1	4 lp/mm
	Cephalometric	4.5 lp/mm – 1x1		4.5 lp/mm
Pixel Size	**CBCT**	200 μm (2x2 binning)	200 μm	C12820DK-40: 240 μm - um2x2 binning
	Panoramic	100 μm	100 μm	C12820DK-40: 120 μm
	Cephalometric	100 μm		100 μm
Detector	**CBCT**	200 μm (2x2 binning)	200 μm	C12820DK-40 :240 um (2x2 binning)
	CBCT FOV	5x5, 12x9.5, 17.5x9.5, 10x9.5, 5x9.5, 17.5x15 cm		5x5, 16x10, 16x18 cm
	Panoramic	100 μm (2x2 binning)	100 μm	C12820DK-40 :120 μm
	Cephalometric	DTX2906 : 100 μm		C10502D-43: 100 μm

8. <u>Discussion of Similarities and Differences:</u>

bright CT dental computed tomography X-ray system described in this 510(k) is similar to the predicate device in its indications for use, performance, materials, and safety characteristics.

The differences include the digital X-ray imagers with different FOV sizes. Performance testing was conducted for the subject device to access whether or not the parameter required for functionalities related to imaging properties of the dental X-ray device meets the designated acceptance criteria. The MTF, DQE and pixel resolution of the subject

device performed similar to or better than those of the predicate device. The pixel resolutions of the subject device in CBCT (2x2 binning) and pano mode are also similar or superior to that of the reference device.

All test results were satisfactory.

9. Non-Clinical Data and Performance Testing

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1(2015, A1:2012), IEC 60601-1-3 (2008 + A1: 2013), IEC 60601-1-6 (2010 + A1: 2013), IEC 60601-2-63 (2012, A1:2017)were performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2.

bright CT meets the provisions of NEMA PS 3.1-3.18, Digital Imaging and Communications in Medicine (DICOM) Set.

Non-clinical & Clinical considerations according to FDA Guidance "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices" were performed.
Acceptance test according to IEC 61223-3-4 and IEC 61223-3-5 was performed.
All test results were satisfactory.

10. Clinical Data: Not required for a finding of substantial equivalence.

11. Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the similarity to the predicate device in terms of technology, performance and indications for use, Dentium Co., Ltd. concludes that the bright CT is substantially equivalent to rainbow CT, the predicate device as described herein.

The differences between the new device and the predicate device shown in the comparison table above do not raise any new questions about safety and effectiveness and so we consider it substantially equivalent to the predicate device.