Dentium Co., Ltd (ICT Branch)
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
7707 Fannin St. Ste 200, V111
HOUSTON TX 77054

April 16, 2021

Re: K200271
Trade/Device Name: rainbow CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: March 10, 2021
Received: March 15, 2021

Dear Mr. 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 (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,

Michael D. O'Hara For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200271

Device Name

rainbow CT

Indications for Use *(Describe)*

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.

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.

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510(k) Summary

K200271

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

1. Date Summary Prepared: March 10, 2021

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)
Official Correspondent: (U.S. Designated agent)	Dave Kim (davekim@mtech-inc.net)
Address:	7707 Fannin St. Ste 200, Houston, TX 77054
Telephone:	+1- 713-467-2607

3. Device:

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

4. Predicate Device:

Legally Marketed Predicate Device Information:

510(k) Number:	K193139
Trade /Proprietary Name:	ProVecta 3D Prime Ceph
Device:	X-Ray, Tomography, Computed, Dental
Regulation Description:	Computed tomography x-ray system.
Review Panel	Radiology
Product Code	OAS
Regulation Number	892.1750
Device Class	2

5. Reference Device:

510(k) Number:	K172614
Manufacturer:	Ray Co., Ltd
Trade / Proprietary Name:	RCT700
Device:	X-Ray, Tomography, Computed, Dental
Regulation Description:	Computed tomography x-ray system.
Review Panel	Radiology
Product Code	OAS
Regulation Number	892.1750
Device Class	2

6. Device Description:

- rainbow 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.

7. Indications for use:

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.

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

Summary of the Technological Characteristics

Descriptive Information		Rainbow CT Dentium Co., Ltd (ICT Branch)	K193139, ProVecta 3D Prime Ceph DÜRR DENTAL SE
Indications for Use		- 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.	ProVecta 3D Prime Ceph is a computed tomography x-ray unit intended to generate 3D, panoramic and cephalometric X-ray images in dental radiography for adult and pediatric patients. It provides diagnostic details of the maxillofacial areas for a dental treatment. The device is operated and used by physicians, dentists, and x-ray technicians. Not intended for mammography use
Image Acquisition Modes		Panoramic, cephalometric and computed tomography	Panoramic and computed tomography
Imaging Software		Rainbow 3D ImageViewer	Vision X includes 2D and 3D
Input Voltage		AC 100-240 V, 50/60 Hz	AC 200-240V
Tube Voltage		60~100 kV	60-99 KV
Tube Current		4~12 mA	4~16mA
Focal Spot Size		0,5 mm	0,5 mm
Exposure Time		Max. 19 s	Max. 20 s
Slice Width		0.1 mm min.	0.1 mm min.
Total Filtration		2.8 mm Al	2.5 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	VistaSoft, DICOM 3.0 compatible
Anatomical Sites		Maxillofacial	Maxillofacial
Image	**CBCT**	C12820DK-40	Xmaru1404CF

Receptor Note: CT and panoramic image performance is identical because the sensors are identical.	**Panoramic**	C12820DK-40	Xmaru1404CF
	MTF@ 1 lp/mm	53%	53%
	DQE @ 0.5 lp/mm	85%	64.%
	Cephalometric	LineScan: C10502D-43	Xmaru 2602CF
Size of Imaging Volume (cm)		C12820DK-40: 5x5, 16x10, 16x18	Xmaru1404CF: Max. 10x8.5
Pixel Resolution	**CBCT**	2 lp/mm – 2x2 binning	2.5 lp/mm - 4x4 binning
	Panoramic	4 lp/mm	2.5 lp/mm - 4x4 binning
	Cephalometric	LineScan: 4.5 lp/mm	Xmaru2602CF
Pixel Size	**CBCT**	C12820DK-40: 240 µm - um2x2 binning	Xmaru1404CF : 99 µm - 2x2 binning 198 µm- 4x4 binning
	Panoramic	C12820DK-40: 120 µm	Xmaru1404CF : 99 µm - 2x2 binning 198 µm- 4x4 binning
	Cephalometric	LineScan: 100 µm	Xmaru2602CF: 200x200µm

9. Summary of technological characteristics of the device compared with the reference device

Descriptive Information		Rainbow CT Dentium Co., Ltd (ICT Branch)	RCT700 (K182614) Ray Co., Ltd
Indications for Use		- 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.	CBCT, panoramic x-ray imaging system with cephalostat, is an extra oral source x-ray system, which is intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry, and it has the capability, using the CBVT technique, to generate dental maxillofacial 3D images. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations. 2D Image is obtained using the standard narrow beam technique.
Detector	**CBCT**	C12820DK-40 :240 um (2x2 binning)	SiX650HD-E: 150 μm
	CBCT FOV	5x5, 16x10, 16x18 cm	5x5, 10x8, 16x10 cm
	Panoramic	C12820DK-40 :120 μm	Six650HD-E: 150 μm C10500D: 100 μm
	Cephalometric	Scan (model: C10502D-43): 100 μm	Scan (model: XID-C24DS): 100 μm One Shot (model: PaxScan 4336X) : 139μm

10. Discussion of Similarities and Differences:

Rainbow 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 and image viewing software. 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 those of the predicate device. The pixel resolutions of the subject device in CBCT (2x2 binning) and pano mode are superior to that of the reference device.

All test results were satisfactory.

11. Non-Clinical Data and Performance Testing

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1(A1+A2, 1995), IEC 60601-1-1 (2001), IEC 60601-1-3 (2008 + A1: 2013), IEC 60601-2-63 (2012)were performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2.

rainbow 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.

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

13. 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 rainbow CT is substantially equivalent to ProVecta 3D Prime with VistaSoft, 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.