December 6, 2022

MegaGen Implant CO., Ltd.
% Yong Jae Kim
Research Engineer
45, Secheon-ro, 7-gil
Daegu, Dasa-eup, Dalesong-gun 42921
KOREA

Re: K222219
Trade/Device Name: R2 Studio Q/RCT820
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: July 18, 2022
Received: November 10, 2022

Dear Yong Jae 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,

Lu Jiang 2022.12.06 07:13:02 -05'00'

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of 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)*

K222219

Device Name
R2 STUDIO Q/RCT820

Indications for Use *(Describe)*

R2 STUDIO Q/RCT820 is CBCT and panoramic x-ray imaging system with cephalometric.
Which is intended to radiographic examination of the dento-maxillofacial, sinus, TMJ, Airway for diagnostic support for adult and pediatric patients. And a model scan is included as an option.
Cephalometric image is also includes wrist to obtain carpus images for growth and maturity assessment for orthodontic treatment.
The device is to be operated and used by dentists or other legally qualified health care professionals.

This device is not intended for use on patients less than approximately 21 kg (46 lb) in weight and 113 cm (44.5 in) in height; these height and weight measurements approximately correspond to that of an average 5 year old.

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) Number: K222219

1. 510(k) Summary

The summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92.

2. Date: July 18, 2022

3. Administrative Information

APPLICANT MegaGen Implant Co., Ltd.

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TEL: +82-53-247-2261
FAX: +82-53-247-2254

Contact Person e-mail: ra3@imegagen.com

4. Device Information

Device Name

Trade/Proprietary Name: R2 STUDIO Q/RCT820
Common Name: Dental panoramic/tomography and cephalometric x-ray system

Classification

Classification Name: Computed tomography x-ray system
Regulation Number: 21 CFR 892.1750
Class: II
Product code: OAS
Panel: Radiology

5. Predicate device & Reference Device

Parameter	Predicate Device	Reference Device
Device Name	RCT800	RCT700
Manufacturer	RAY Co., Ltd	RAY Co., Ltd
510(k) Number	K192737	K213226
Classification name	Computed tomography x-ray system	Computed tomography x-ray system
Regulation number	892.1750	892.1750
Primary product code	OAS	OAS

7. Device Description

System purpose R2 STUDIO Q/RCT820 is 3D computed tomography for scanning hard tissues like bone and teeth. By rotating the c-arm which is embedded with high voltage generator all-in-one x-ray tube and a detector on each end, CBCT images of dental maxillofacial is attained by recombining data from the same level that are scanned from different angle.

Panoramic image scanning function for attaining image of whole teeth, cephalometric scanning option for attaining cephalic image are included. and Model Scan option for attaining dental model CBCT image are included.

8. Indication for use

R2 STUDIO Q/RCT820 is CBCT and panoramic x-ray imaging system with cephalometric.
Which is intended to radiographic examination of the dento-maxillofacial, sinus, TMJ, Airway for diagnostic support for adult and pediatric patients. And a model scan is included as an option.
Cephalometric image is also includes wrist to obtain carpus images for growth and maturity assessment for orthodontic treatment.
The device is to be operated and used by dentists or other legally qualified heath care professionals.

This device is not intended for use on patients less than approximately 21 kg (46 lb) in weight and 113 cm (44.5 in) in height; these height and weight measurements approximately correspond to that of an average 5 year old.

9. Patient population

The patient population can be the possible person who can be taken X-ray diagnostic radiation exposure.
There is no restriction for ethnic group, Gender, weight, health, or condition.
We recommend patients for x-ray diagnostic radiation exposure to be over 5 years old.

10. Operating principle

The purpose of this unit is diagnose clinical structures of a tooth and head areas mainly by using the characteristics of permeability from X-ray. The principle of functioning and formations are as following. The machine is made of X-ray generator and arms in which transfers X-ray signals to a sensor in 2D. Also, an object that has a magnification is required in a distance. Moreover, the unit has to be adjustable depending on height of a patient and PC system to reconstruct an image. The arm parts are controlled for rotating and linear moving to synchronize between the sensor and X-ray generator to get the image of interests. The purpose of this mechanism is to provide the images in 2D or/and 3D as preferred to diagnose in a monitor. CBCT provides in 3D images as reconstructed and Panorama is to diagnose the structures in a panoramic view. Cephalometric allows for orthodontic treatment. These 3 functions could be in 1 system, Panorama with Cephalometric, or Panorama only system depending on the needs. To provide the features as mentioned above, digital transferring from permeated X-ray to absorbing to the sensor is essential and all the process are proceed in Detector. Detector transfers X-ray to light depending on the structure materials. Detector is separated into indirect method that the light is changed to digital signals on photodiode and direct method in which the light is directly transferred to digital signal. This unit is using both direct and indirect method depending on the interior structure materials.

11. Comparison with predicate devices

The following table provides the summary of the technological characteristics of R2 STUDIO Q/RCT820 compared to the predicate device and Reference Device.

Parameter	Proposed Device	Predicate Device	Reference Device
Manufacturer	MegaGen Implant Co., Ltd.	RAY Co., Ltd.	RAY Co., Ltd.
Device name	R2 STUDIO Q/RCT820	RCT800	RCT700
510(k) Number	- (Traditional 510(k))	K192737 (Traditional 510(k))	K213226 (Traditional 510(k))
Common Name	Dental panoramic/tomography and cephalometric x-ray system	Dental panoramic/tomography and cephalometric x-ray system	Dental panoramic/tomography and cephalometric x-ray system
Indications for use	R2 STUDIO Q/RCT820 is CBCT and panoramic x-ray imaging system with cephalometric. Which is intended to radiographic examination of the dento-maxillofacial, sinus, TMJ, Airway for diagnostic support for adult and pediatric patients. And a model scan is included as an option. Cephalometric image is also includes wrist to obtain carpus images for growth and maturity assessment for orthodontic treatment. The device is to be operated and used by dentists or other legally qualified heath care professionals. This device is not intended for use on patients less than approximately 21 kg (46 lb) in weight and 113 cm (44.5 in) in height; these height and weight measurements approximately correspond to that of an average 5 year old.	RCT800 is CBCT and panoramic x-ray imaging system with cephalometric. Which is intended to radiographic examination of the dento-maxillofacial, sinus, TMJ, Airway for diagnostic support for adult and pediatric patients. And a model scan is included as an option. Cephalometric image is also includes wrist to obtain carpus images for growth and maturity assessment for orthodontic treatment. The device is to be operated and used by dentists or other legally qualified heath care professionals.	RCT700 is CBCT and panoramic x-ray imaging system with cephalometric. Which is intended to radiographic examination of the dento-maxillofacial, sinus, TMJ, Airway and ENT structure for diagnostic support for adult and pediatric patients. And a model scan is included as an option. Cephalometric image is also includes wrist to obtain carpus images for growth and maturity assessment for orthodontic treatment. The device is to be operated and used by dentists or other legally qualified heath care professionals.
Mode of Operation	Continuous operation with intermittent, stated permissible loading	Continuous operation with intermittent, stated permissible loading	Continuous operation with intermittent, stated permissible loading
3D technology	CBCT Cone beam Computed Tomography	CBCT Cone beam Computed Tomography	CBCT Cone beam Computed Tomography
Performance Specification	1) CBCT Computed tomography - Patient - Dental Model Scan(Optional) 2) Panoramic 3) Cephalometric(optional) - Scan type	1) CBCT Computed tomography - Patient - Dental Model Scan(Optional) 2) Panoramic 3) Cephalometric(optional) - One shot type	1) CBCT Computed tomography - Patient 2) Panoramic 3) Cephalometric(optional) - One shot type - Scan type

			- Scan type	
Functional Option		Base CT + PANO Option(CEPH) CT + PANO + SCAN CEPH	Base CT + PANO Option(CEPH) CT + PANO + SCAN CEPH CT + PANO + One shot(One shot, Standard Type) CT + PANO + One shot(One shot, Large Type)	Base CT + PANO Option(CEPH) CT + PANO + SCAN CEPH CT + PANO + One shot(One shot, Standard Type) CT + PANO + One shot(One shot, Large Type)
Detector Type	CT	FXDD-1724R	FXDD-0606CA	FXDD-0606CA
			FXDD-1012CHA	Jupi0606X
	PANO	FXDD-1724R	FXDD-0606CA	FXDD-0606CA
			FXDD-1012CHA	Jupi0606X
	Ceph (Scan)	XID-C24DC	XID-C24DC	XID-C24DC
	Ceph (One shot)	N/A	1717SCC	FXRD-1717VA
		N/A	PaxScan2530C	FXDD1012CA
Exposure switch Type		“Deadman” Button type	“Deadman” Button type	“Deadman” Button type
Main Components		Ceph Apparatus	Ceph Apparatus	Ceph Apparatus
		Vertical Carriage	Vertical Carriage	Vertical Carriage
		Rotator	Rotator	Rotator
		X-RAY Generator	X-RAY Generator	X-RAY Generator
		X-ray tube	X-ray tube	X-ray tube
		High Frequency Generator	High Frequency Generator	High Frequency Generator
		Column	Column	Column
		Touch monitor (panel)	Touch monitor (panel)	Touch monitor (panel)
		Detector - CT FXDD-1724R - PANO FXDD-1724R - Ceph XID-C24DC(Scan)	Detector - CT FXDD-0606CA FXDD-1012CHA - PANO FXDD-0606CA FXDD-1012CHA - Ceph XID-C24DC(Scan) PaxScan 2530C(One shot, Standard Size) 1717SCC(One shot, Large Size)	Detector - CT FXDD-0606CA Jupi0606X - PANO FXDD-0606CA Jupi0606X -Ceph XID-C24DC(Scan) FXDD-1012CA(One shot, Standard Size) FXRD-1717VA(Oneshot, Large Size)

		Chinrest	Chinrest	Chinrest
		Head rest	Head rest	Head rest
		Automatic Collimator	Automatic Collimator	Automatic Collimator
		Exposure switch	Exposure switch	Exposure switch
		Emergency stop switch	Emergency stop switch	Emergency stop switch
		Console PC set	Console PC set	Console PC set
Automatic Collimator		CT exams Panoramic exams Cephalometric exams	CT exams Panoramic exams Cephalometric exams	CT exams Panoramic exams Cephalometric exams
Display Type		TFT LCD type(Normally black) *1280x800 pixel	TFT LCD type(Normally black) *1280x800 pixel	TFT LCD type(Normally black) *1280x800 pixel
Class		Class I with type B applied parts according to IEC 60601-1	Class I with type B applied parts according to IEC 60601-1	Class I with type B applied parts according to IEC 60601-1
Focal size		0.5(Patient/Model scan)	0.5(Patient) 0.04 (Model scan)	0.5
Field of View(CT)		Max. 180x160 mm	FXDD-0606CA : Max. 160x100 mm FXDD-1012CHA : Max. 200x200 mm	Max. 160x100 mm
X-ray Voltage(Patient)		60~100kVp	60~100kVp	60~100kVp
X-ray Current(Patient)		1~17mA	4~17mA	1~17mA
X-ray Voltage(Model Scan, Optional)		N/A	50~80kVp	N/A
X-ray Current(Model Scan, Optional)		N/A	0.4~0.7mA	N/A
Total Filtration		Min. 2.8 mm Al equivalent	Min. 2.8 mm Al equivalent	Min. 2.8 mm Al equivalent
Detector Pixel size	CT	FXDD-1724R : 95 µm	FXDD-0606CA : 119 µm	FXDD-0606CA : 119µm
		N/A	FXDD-1012CHA : 124 µm	Jupi0606X : 100 µm
	PANO	FXDD-1724R : 95 µm	FXDD-0606CA : 119 µm	FXDD-0606CA : 119 µm
		N/A	FXDD-1012CHA : 124 µm	Jupi0606X : 100 µm
	Ceph (Scan)	XID-C24DC : 100 µm	XID-C24DC : 100 µm	XID-C24DC : 100 µm
	Ceph (One shot)	N/A	1717SCC : 127 µm	FXRD-1717VA : 140 µm
		N/A	PaxScan 2530C : 139 µm	FXDD-1012CA : 124 µm
Magnification	CT	1.44(Patient/Model scan)	1.44(Patient) 1.91(Model Scan)	1.44
	PANO	1.35	1.3	1.31
	Ceph (Scan)	1.11	1.11	1.11
	Ceph (One shot)	N/A	Standard Size : 1.12	Standard Size : 1.12
		N/A	Large Size : 1.13	Large Size : 1.13
Scan time		CT: below 20sec (Patient/Model scan)	CT : below 20sec(Patient) CT : below 180sec(Model Scan)	CT : below 14sec
		Pano : below 14sec	Pano : below 14sec	Pano : below 14sec
		Ceph(Scan) : below 20sec	Ceph[Scan type] : below 20sec	Ceph[Scan type] : below 20sec

	N/A	Ceph[One shot type] : below 2sec	Ceph[One shot type] : below 2sec
Format compatible	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible
Image Viewing Software	R2 STUDIO Q	RayScan (Cleared under K192737)	RayScan (Cleared under K182614)
Image acquisition	Giga-Ethernet Network	Giga-Ethernet Network	Giga-Ethernet Network
Total Height	Max 2,296mm	Max 2,296mm	Max 2,296mm
Weight	1) Computed Tomography(CT) + Panoramic(PANO) = 240kg(529.1lb) ± 10% 2) Computed Tomography(CT) + Panoramic(PANO) + Ceph(Scan type) = 270kg(595.2lb) ± 10%	1) Computed Tomography(CT) + Panoramic(PANO) = 189kg(416.6lb) ± 10% 2) Computed Tomography(CT) + Panoramic(PANO) + Ceph(Scan type) = 219kg(482.8lb) ± 10% 3) Computed Tomography(CT) + Panoramic(PANO) + Ceph(One shot type, installed in Standard size) = 217kg(478.4lb) ± 10% 4) Computed Tomography(CT) + Panoramic(PANO) + Ceph(One shot type, installed in Large size) = 212kg(467.3lb) ± 10%	1) Computed Tomography(CT) + Panoramic(PANO) = 185kg(407.9lb) ± 10% 2) Computed Tomography(CT) + Panoramic(PANO) + Ceph(Scan type) = 212.5kg(468.5lb) ± 10% 3) Computed Tomography(CT) + Panoramic(PANO) + Ceph(One shot type, installed in Standard size) = 211kg(465.2lb) ± 10% 4) Computed Tomography(CT) + Panoramic(PANO) + Ceph(One shot type, installed in Large size) = 211kg(465.2lb) ± 10%
Type of installation	Wall or floor mount	Wall or floor mount	Wall or floor mount
Patient position	Standing / Wheelchair	Standing / Wheelchair	Standing / Wheelchair
Face scan mode	Option	Option	NA
Applicable Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-2-63	IEC 60601-1 IEC 60601-1-3 IEC 60601-2-63 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-3 IEC 60601-2-63 IEC 60601-1-2

Similarities and differences

1. <u>Similarities</u>

The subject device has the same characteristic for the following compared to the predicate device and reference device

- Indication for use, mode of operation, 3D technology, performance specification, functional option, exposure switch type, main components(except for detector), automatic collimator, display type, class, focal size, X-ray voltage(patient), X-ray current(patient), total filtration, magnification(CT, Ceph), scan time, format compatible, image acquisition, total height, type of installation, patient position, applicable standards

2. <u>Differences</u>

The subject device has the different characteristic for the following compared to the predicate device and reference device

- Detector (using for CT, PANO), Field of view, magnification(PANO),Weight, Image Viewing Software

12. Safety and Effectiveness Information

RCT820 system described in this 510(k) is similar to the predicate device in terms of indications for use, materials, safety characteristics, and X-ray source.
The fundamental technological characteristics of the subject and predicate device are similar. The imaging modes are similar; PANO, CEPH (Optional), CBCT, Model Scan.

The differences are as follows.

- Detector (using for CT, PANO), Field of view, magnification (PANO)
- Weight
- Image Viewing Software

These differences are explained not affecting on the substantial equivalence, also the subject device was verified with non-clinical performance test and clinical test. The test result supports that the subject device is substantially equivalent to the predicate device and the differences are not affecting the substantial equivalence.

Biocompatibility Testing

The biocompatibility evaluation for RCT820 components was conducted in accordance with the FDA Guidance Document and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part1: Evaluation and Testing within a Risk Management Process ", as recognized by FDA.
The components of the RCT820 are considered surface medical device or external communicating medical device for a duration of less than 24 hours.
The biocompatibility testing was performed for Cytotoxicity, Skin sensitization and Irritation according to ISO 10993-5 and ISO 10993-10.

Electrical Safety and Electromagnetic compatibility (EMC)

The Electrical Safety and Electromagnetic compatibility were performed in accordance with the following standards.

- IEC 60601-1:2005/AMD1:2012
- IEC 60601-1-3:2008/AMD1:2013
- IEC 60601-1-6:2010/AMD1:2013
- IEC 60601-2-63:2017/AMD1:2017
- IEC 60601-1-2: 2014

Software Validation

The software(named R2 STUDIO Q) used in the subject device has an imaging viewing option similar to the predicate devices software. Likewise, the software of RCT820 saves the patient and image data and offers an inquiry function. In addition, supports the image generate function intended to obtain images using the RCT820 equipment and various sensors for diagnosis. And that has been validated according to FDA "Guidance for the Contents of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" to assure substantial equivalence. The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the

software would not directly result in serious injury or death to the patient or operator. As a result, we identified the level of concern associated with new device and provided documentation consistent with that level. Based on our risk analysis of software, the difference does not affect its safety and effectiveness.

Performance Test – Bench Test

Bench testing was conducted according to FDA Guidance “Format for Traditional and Abbreviated 510(k)s, section 18, Performance Testing – Bench”. Bench testing is used to assess whether or not the parameter measured required for describing functionalities related to imaging properties of the dental X-ray device and patient dosage satisfies the designated tolerance. Performance (Imaging performance) testing was conducted according to standard of IEC 61223-3-4 and IEC 61223-3-7.
All test results were satisfactory.

Non-clinical considerations were conducted in accordance with FDA Guidance "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices".
RCT820 is equipped with FXDD-1724R. FXDD-1724R is a new SSXI detector, which is used to capture an image in panoramic, CBCT. Sample images with a clinical evaluation report is provided to support the intended use of the device.
Based on Non-Clinical and Clinical Test results of FXDD-1724R for the subject device, is similar to that of the Jupi0606X for the reference device.

Pediatric Information

Pediatric information related to the use of this device is provided to users in compliance with FDA guidance “Pediatric Information for X-ray Imaging Device Premarket Notifications”.

13. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification. MegaGen Implant Co., Ltd. concludes that the newly RCT820 is safe and effective and substantially equivalent to the predicate devices as described herein.