October 25, 2024

VATECH Co., Ltd
% Dave Kim
RA Consultant
Mtech Group LLC
7505 Fannin St. Suite 610
HOUSTON, TX 77054

Re: K240040
Trade/Device Name: VistaPano S Ceph 2.0 (VistaPano S Ceph)
VistaPano S 2.0 (VistaPano S)
ProVecta S-Pan Ceph 2.0 (ProVecta S-Pan Ceph)
ProVecta S-Pan 2.0 (ProVecta S-Pan)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: MUH
Dated: September 24, 2024
Received: September 25, 2024

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.

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)*

K240040

Device Name

VistaPano S Ceph 2.0 (VistaPano S Ceph);
VistaPano S 2.0 (VistaPano S);
ProVecta S-Pan Ceph 2.0 (ProVecta S-Pan Ceph);
ProVecta S-Pan 2.0 (ProVecta S-Pan)

Indications for Use *(Describe)*

The unit is intended to produce panoramic or cephalometric digital x-ray images. It provides diagnostic details of the dento-maxillofacial, sinus and TMJ for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The device is to be operated by physicians, dentists, and x-ray technicians.

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
K240040

1. 510(k) Summary

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

2. Date 510K Summary prepared: September 24, 2024

3. Administrative Information

Official Correspondent:	Mtech Group LLC 7505 Fannin St. Suite 610, Houston, TX 77054 Tel: +713-467-2607 Contact person: Mr. Dave Kim (davekim@mtechgroupllc.com)
510(k) Submitter:	VATECH Co., Ltd. Address: 13, Samsung 1-ro 2-gil, Hwaseong-si, Gyeonggi-do, 18449, Korea Tel: +82-31-379-9492 Fax: +82-31-379-9400 Contact person: Daniel Kim / Manager (daniel.kim@vatech.com)

4. Device Information

Type of 510(k) Submission:	Traditional
Trade or Proprietary Name:	VistaPano S Ceph 2.0 (VistaPano S Ceph) VistaPano S 2.0 (VistaPano S) ProVecta S-Pan Ceph 2.0 (ProVecta S-Pan Ceph) ProVecta S-Pan 2.0 (ProVecta S-Pan)
Common or Usual Name:	Digital X-ray Imaging System
Regulation Classification:	Extraoral source x-ray system (21 CFR 872.1800)
Product Code:	MUH
Class of Device:	Class II
Panel:	Radiology

5. Predicate Device Information

Manufacturer:	VATECH Co., Ltd.
Predicate device:	PaX-i Plus/PaX-i Insight (Model: PCH-30CS) / K170731
Common or Usual Name:	Digital X-ray Imaging System
Regulation Classification:	Extraoral source x-ray system (21 CFR 872.1800)
Product Code:	MUH
Class of Device:	Class II
Panel:	Radiology

6. Reference Device Information

Manufacturer:	VATECH Co., Ltd.
Reference device:	Green X 12 (Model: PHT-75CHS) / K231796
Common or Usual Name:	Digital X-ray Imaging System
Regulation Classification:	Computed tomography x-ray system (21 CFR 892.1750)
Product Code:	OAS
Class of Device:	Class II
Panel:	Radiology

7. Device Description

The device is an advanced 2-in-1 digital X-ray imaging system that incorporates PANO and CEPH (Optional) imaging capabilities into a single system and acquires 2D diagnostic image data in conventional panoramic and cephalometric modes.
The device is not intended for CBCT imaging.

VistaPano S is identified as panoramic-only models for VistaPano S Ceph.
ProVecta S-Pan Ceph and ProVecta S-Pan are alternative model for VistaPano S Ceph and VistaPano S respectively.
The subject device has different model names designated for different US distributors:

- VistaPano S Ceph, VistaPano S: DÜRR DENTAL
- ProVecta S-Pan Ceph, ProVecta S-Pan: AIR TECHNIQUES

Key components of the device

1) VistaPano S Ceph 2.0 (Model: VistaPano S Ceph), VistaPano S 2.0 (Model: VistaPano S) digital x-ray equipment (Alternate: ProVecta S-Pan Ceph 2.0 (Model: ProVecta S-Pan Ceph), ProVecta S-Pan 2.0 (Model: ProVecta S-Pan))

2) SSXI detector: Xmaru1501CF-PLUS, Xmaru2602CF

Item	Description	
	PANO (VistaPano S 2.0 / ProVecta S-Pan 2.0)	**CEPH (VistaPano S Ceph 2.0 / ProVecta S-Pan Ceph 2.0)**
Model	Xmaru1501CF-PLUS	Xmaru2602CF
Detector Type	CMOS photodiode array	CMOS photodiode array
Pixel Size	100 µm	100 µm- Non binning 200 µm -2X2 binning
Active Area	151.2 x 6.0 mm	259 x 15.6 mm
Frame Rate	~287 fps	~109 fps (Non binning) ~330 fps (2x2 Binning)
Analogue-Digital Conversion	14 bits	14 bits
Converter	CsI:Ti	CsI:Ti
Energy Range	50 ~ 120 kV	50 ~ 120 kV

Item	Description	
	PANO (VistaPano S 2.0 / ProVecta S-Pan 2.0)	**CEPH (VistaPano S Ceph 2.0 / ProVecta S-Pan Ceph 2.0)**
Readout Type	Charge amplifier array	Charge amplifier array
Video Output	Optic	Optic

3) X-ray generator

Item			Description
High Voltage Generator	Model		DG-07E22T2
	Rated output power		1.6 kW
	Type		Inverter
	Normal/Pulse	kV	60 ~ 99 kV (1 kV increment)
		mA	4 ~ 16 mA (1 mA increment for PANO and CEPH)
	Cooling		Thermals protect
	Total filtration		Min. 2.5 mm Al
	Added filter		1.5 mm Al
X-ray Tube	Manufacturer		Canon Electron Tubes & Devices
	Model		D-052SB (Stationary Anode type)
	Focal spot size		0.5 x 0.5 mm
	Target Angle		5 degrees
	Inherent Filtration		At least 0.8 mm Al equivalent at 50 kV
	Anode Heat Content		35 kJ
	Duty Cycle		1:60 or more (Exposure time : Interval time)

Note: The subject device has the same X-ray generator as the reference device (K231796).

4) PC system

Item	Description
Operating System	Windows 10 Professional 64-Bit OS or higher
CPU	Intel® Core i5-8500 6C
RAM	16GB (2x8 GB) DDR4-2666 ECC REG APJ or Larger
HDD	1TB SATA 7200 rpm * 2EA
Graphics board	GEFORCE RTX1060 Graphics
Ethernet interface	Broadcom 5761 Gigabit PCIe NIC
Serial Port (RS232)	HP Serial Port Adapter Kit
Power Supply	500W internal power module, up to 90% efficiency, active PFC
Slots	1 ports PCIe 3 x4 2 ports M.2 PCIe 3 x4 1 ports PCIe x1 (x4 open ended connector) 1 ports PCIe x16

5) Imaging software

Item	Description
Image Viewing Program	VisionX 3.0 (K213326)

8. Indications for use

The unit is intended to produce panoramic or cephalometric digital x-ray images. It provides diagnostic details of the dento-maxillofacial, sinus and TMJ for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The device is to be operated by physicians, dentists, and x-ray technicians.

9. Comparison of Technological characteristics with the predicate device

	Subject Device	Predicate Device
Device Name	VistaPano S Ceph 2.0 (Model: VistaPano S Ceph) VistaPano S 2.0 (Model: VistaPano S) ProVecta S-Pan Ceph 2.0 (Model: ProVecta S-Pan Ceph) ProVecta S-Pan 2.0 (Model: ProVecta S-Pan)	PaX-i Plus / PaX-i Insight (Model: PCH-30CS)
Applicant Name	VATECH Co., Ltd.	VATECH Co., Ltd.
510(k) Number	K240040	K170731
Device Classification Name	System, X-Ray, Extra oral Source, Digital	System, X-Ray, Extra oral Source, Digital
Classification Product Code	MUH	MUH
Regulation Number	21 CFR 872.1800	21 CFR 872.1800
Indications for Use	The unit is intended to produce panoramic or cephalometric digital x-ray images. It provides diagnostic details of the dento-maxillofacial, sinus and TMJ for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The device is to be operated by physicians, dentists, and x-ray technicians.	PCH-30CS is intended to produce panoramic or cephalometric digital x-ray images. It provides diagnostic details of the dento-maxillofacial, sinus and TMJ for adult and pediatric patients. The system also utilizes carpal images for orthodontic treatment. The device is to be operated by physicians, dentists, and x-ray technicians.
Performance Specification	Panoramic, Cephalometric	Panoramic, Cephalometric
Input Voltage	AC 200-240 V	AC 100 - 240 V
X-Ray source	D-052SB	D-052SB
Tube Voltage	60 - 99 kV	60 - 99 kV
Tube Current	4 - 16 mA	4 - 10 mA
Focal Spot Size	0.5 x 0.5 mm	0.5 x 0.5 mm
Exposure Time	Max. 13.5 s	Max. 20.2 s
Slice Width	Min. 0.1 mm	Min. 0.1 mm
Total Filtration	Min. 2.5 mm Al	Min. 2.5 mm Al
Mechanical	Compact design	Compact design
Electrical	LDCP logic circuit	LDCP logic circuit
Software	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible

		Subject Device		Predicate Device	
Image Viewing Program		VisionX 3.0 (K213326)		EasyDent (Cleared under K122155)	
				EzDent-i (K163533)	
Anatomical Sites		Maxillofacial		Maxillofacial	
Image Receptor	**PANO**	Xmaru1501CF-PLUS		Xmaru1501CF-PLUS	
				Xmaru1404CF-PLUS	
	CEPH	Xmaru2602CF		Xmaru2602CF	
Pixel Resolution	**PANO**	Xmaru1501CF-PLUS	5 lp/mm	Xmaru1501CF-PLUS	5 lp/mm
				Xmaru1404CF- PLUS	5 lp/mm -2x2 binning (detector spec, Not system spec) 2.5 lp/mm -4x4 binning (system spec)
	CEPH	5 lp/mm-Non binning 2.5 lp/mm -2x2 binning		2.5 lp/mm -2x2 binning (system spec)	
Pixel Size	**PANO**	Xmaru1501CF-PLUS	100 µm	Xmaru1501CF-PLUS	100 µm
				Xmaru1404CF- PLUS	198 µm - 4X4 binning (system spec)
	CEPH	100 µm- Non binning 200 µm -2X2 binning		200 µm -2X2 binning (system spec)	

10. Performance Data

Summary of Performance Testing

The device described in this 510(k) is similar to the predicate device in terms of indications for use, materials, safety characteristics, X-ray source, and Image Receptor.

The following information further substantiates the substantial equivalence between the subject device and predicate device:

a. The fundamental technological characteristics of the subject and predicate device are similar.
b. The imaging modes are same; PANO and CEPH (Optional).
c. The same x-ray source.
d. The same image receptor for PANO imaging mode.

The sponsor tested the subject device in a laboratory. The same test protocol was used to test the performance of the subject and the predicate device for comparison. The sponsor certifies that adequate design and development controls (according to 21 CFR 820.30) were in place for manufacturing the subject device.

The differences between the subject device and the predicate device:

a. The subject device is equipped with the Xmaru2602CF detector which has been cleared with predicate device and added Non binning mode for system specification.
b. The materials of the subject device's components such as temple support cushion, chin holder for bite block & comfort bite holder, bite block and comfort bite holder, comfort bite foam, sanitary vinyl cover are different than the predicate device. The biocompatibility testing for the subject device 's positioning aids has been updated according to the latest ISO 10993-1 standard. The biocompatibility testing results showed that the device's accessory part are biocompatible and safe for its intended use. In addition, ProVect S-Pan Ceph and ProVecta S-Pan products use separate sanitary vinyl covers approved by FDA (K151123).
c. The solid state X-ray imagers (SSXI), Xmaru1501CF-PLUS and Xmaru2602CF, for the subject device are the same SSXI used for the predicate device, K170731. For the Xmaru2602CF detector, the predicate device as an X-ray system used 2x2 binning only in CEPH mode whereas the subject device uses both 2x2 binning and non-binning in CEPH mode. The subject device provides the user with HD mode (non-binning) and SD mode (2x2 binning) options when capturing X-ray images in CEPH mode.
Based on Non-Clinical Test results of Xmaru2602CF detector for the subject device, the bench testing data shows better performance for the Non binning mode compared to 2x2 binning mode.

In addition, the dosimetric performance of the subject device and the predicate device was compared in terms of DAP. With similar FDD(Focal Spot to Detector Distance), DAP measurement in the PANO mode of each device under the same X-ray exposure conditions (exposure time, tube voltage, tube current) was similar.
In CEPH mode, the subject device has two imaging mode options, HD and SD, based on the exposure condition (exposure time, tube voltage, tube current), and the predicate device has also two image options, Normal and Fast. The SD mode of the subject device uses the same 2x2 binning mode as the predicate device and the X-ray exposure conditions (exposure time, tube voltage, tube current) are the same with the Fast mode of the predicate device. The HD mode (non-binning mode) of the subject device requires increased exposure time under the same kVp and mA exposure condition with the Xmaru2602CF detector. Any adjustment of the exposure setting in HD and SD mode of the subject device should consider the patient exposure level to be as low as possible.

The image quality performance of non-binning mode has been evaluated in terms of the measured line pair resolution and contrast data using phantoms. As a result, the HD mode (non-binning mode) of the subject device performed better or equivalent in line pair resolution than the predicate device.

Clinical images obtained from the subject and predicate devices are evaluated and compared and demonstrate that the general image quality of the subject device is equivalent or better than the predicate device.

Clinical and non-clinical evaluation results of the subject device provide further evidence in addition to the laboratory performance data to show that the complete system works as intended.

The following FDA guidance has been utilized in the development of the subject device:

- *"Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices"*

- *"Pediatric Information for X-ray Imaging Device Premarket Notifications, Guidance for Industry and Food and Drug Administration Staff, November 2017,"*

Software Verification and Validation Testing

Software verification and validation were conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." 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.
The following cyber security guidance was applied in the development of the subject device:

- *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".*

The device provides the following image viewing programs;

- Image viewing program: VisionX 3.0 (K213326)

Safety, EMC and Performance Data

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Edition 3.2), IEC 60601-1-3:2008+AMD1:2013+AMD2:2021 (Edition 2.2), IEC 60601-2- 63:2012+AMD1:2017+AMD2:2021 (Edition 1.2) were performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2:2014+AMD1:2020 (Edition 4.1). The manufacturing facility is in conformance with the relevant EPRC standards as specified in 21 CFR 1020.30, 31 and the records are available for review. The device conforms to the provisions of NEMA PS 3.1-3.18, Digital Imaging and Communications in Medicine (DICOM) Set.
Non-clinical consideration in accordance with the FDA guidelines "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices" was provided.
Bench testing according to FDA Guidance "Format for Traditional and Abbreviated 510(k)s, Performance Testing – Bench" were performed. Image evaluation according to IEC 61223-3-4 were also performed.

All test results were satisfactory.

11. Conclusions

The proposed device and the predicate device have same indications for use and demonstrated similar technical characteristics. The applied image receptor for PANO and CEPH mode was previously cleared by the predicate device, PCH-30CS (K170731). The subject device added the HD mode, utilizing the non-binning capability of the Xmaru2602CF detector in CEPH mode. As demonstrated in the subject device performance test, the detector Xmaru2602CF with non-binning mode added to the system specifications performed similarly or better in comparison with the predicate device. Quality assurance procedures are adhered to, and the specifications and functional requirements were met as the test results indicated.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, VATECH Co., Ltd. concludes that the subject device (VistaPano S Ceph 2.0 (Model: VistaPano S Ceph), VistaPano S 2.0 (Model: VistaPano S), ProVecta S-Pan Ceph 2.0 (Model: ProVecta S-Pan Ceph), ProVecta S-Pan 2.0 (Model: ProVecta S-Pan))is substantially equivalent to the predicate device as described herein.