Durr Dental SE
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

August 2nd, 2018

Re: K181432
Trade/Device Name: ProVectra 3D Prime with VistaSoft
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: May 29, 2018
Received: June 1, 2018

Dear Mr. Kamm:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K181432

Device Name
ProVectra 3D Prime with VistaSoft

Indications for Use *(Describe)*

ProVecta 3D Prime:

ProVecta 3D Prime is computed tomography x-ray unit intended to generate 3D and panoramic 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.

VistaSoft:

The VistaSoft software features functions for recording, displaying, analyzing, diagnosing, managing and sending digital or digitized video and X-ray images in dental practices and specialist dental clinics.
Not intended for mammography use.

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, DÜRR DENTAL SE, ProVecta 3D Prime with VistaSoft

K181432

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

1. Date Summary Prepared:

July 26, 2018

2. Submitter's Identification:

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3. Device:

Trade /Proprietary Name:	ProVecta 3D Prime with VistaSoft
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:

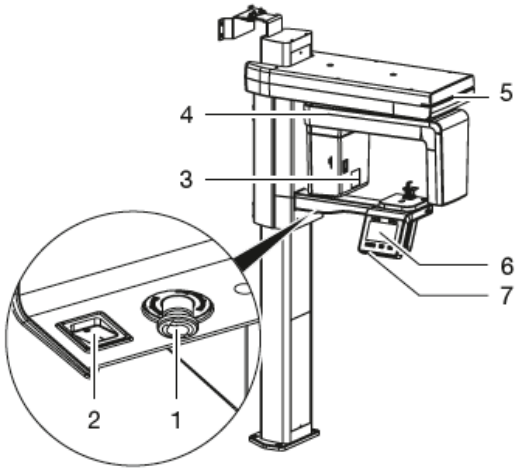
510(k) Number:	K152106
Manufacturer:	Vatech Co. Ltd.
Trade /Proprietary Name	PaX-i3D Smart (PHT-30LFO)
Device:	X-Ray, Tomography, Computed, Dental

Regulation Description:	Computed tomography x-ray system.
Regulation Medical Specialty:	Radiology
Review Panel	Radiology
Product Code	OAS
Regulation Number	892.1750
Device Class	2

The Dental tomography x-ray system requires our VistaSoft Software, modified from what was cleared in: K161444
Trade/Device Name: DBSWIN and VistaEasy Imaging Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ

5. <u>Device Description:</u>

This device is a cone beam CT x-ray device for the acquisition of dental images. Similar to computer tomography or magnetic resonance tomography, sectional images can be generated with CBCT. With CBCT, an X-ray tube and an imaging sensor opposite it rotate around a seated or standing patient. The X-ray tube rotates through 180°-540° and emits a conical X-ray beam. The X-rays pass through the region under investigation and are measured for image generation by a detector as an attenuated grey scale X-ray image. Here, a large series of two-dimensional individual images is acquired during the revolution of the X-ray tube. Using a mathematical calculation on the rotating image series via a reconstruction computer, a grey value coordinate image is generated in the three spatial dimensions. This three-dimensional coordinate model corresponds to a volume graphic that is made up of individual voxels. This volume can be used to generate sectional images (tomograms) in all spatial dimensions as well as 3D views. The system complies with US Radiation Safety Performance Standard.



1 Emergency stop switch
2 On/off switch
3 X-ray tube
4 C-shaped elbow
5 Status LED
6 Operating elements
7 Memory card slot

6. Indications for use:

ProVecta 3D Prime is computed tomography x-ray unit intended to generate 3D and panoramic 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.
The VistaSoft software features functions for recording, displaying, analyzing, diagnosing, managing and sending digital or digitized video and X-ray images in dental practices and specialist dental clinics. Not intended for mammography use.

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

Summary of the Technological Characteristics

Descriptive Information	**K152106, PaX-i3D Smart (PHT-30LFO) Vatech Co., Ltd.**	**ProVecta 3D Prime with VistaSoft DÜRR DENTAL SE**
Indications for Use	PHT-30LFO is a computed tomography x-ray system intended to produce panoramic, cephalometric or cross-sectional images of the oral anatomy on a real time basis by computer reconstruction of x-ray image data from the same axial plane taken at different angles. It provides diagnostic details of the anatomic structures by acquiring 360° rotational image sequences of oral and maxillofacial area for a precise treatment planning in adult and pediatric dentistry. The device is operated and used by physicians, dentists, and x-ray technicians.	ProVecta 3D Prime is computed tomography x-ray unit intended to generate 3D and panoramic 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. The VistaSoft software features functions for recording, displaying, analyzing, diagnosing, managing and sending digital or digitized video and X-ray images in dental practices and specialist dental clinics. Not intended for mammography use. Main difference: This unit does not support the cephalometric mode.
Image Acquisition Modes	Panoramic, cephalometric and computed tomography	Panoramic and computed tomography
Imaging Software	EasyDent: 2D viewer and patient management software Ez3D Plus : 3D viewer and image analysis software	VistaSoft, includes 2D and 3D
Input Voltage	AC 100-240 V	AC 200-240V
Tube Voltage	50-99 kV	50-99 KV
Tube Current	4 ~16 mA	4~16mA

Descriptive Information		K152106, PaX-i3D Smart (PHT-30LFO) Vatech Co., Ltd.	ProVecta 3D Prime with VistaSoft DÜRR DENTAL SE
Focal Spot Size		0.5 mm	0,5 mm
Exposure Time		Max. 18 s	Max. 16.4s
Slice Width		0.1 mm min.	0.1 mm min.
Total Filtration		2.8 mm Al	2.8 mm Al
Chin Rest		Equipped 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		DICOM 3.0 Format compatible	VistaSoft, DICOM 3.0 compatible
2D Image Viewing Program		EasyDent	VistaSoft
3D Image Viewing Program		Ez3D Plus	VistaSoft
Anatomical Sites		Maxillofacial	Maxillofacial
Image Receptor Note: CT and panoramic image performance is identical because the sensors are identical.	**Computed Tomography**	Xmaru1404CF	Xmaru1404CF
	Panoramic	Xmaru1404CF	Xmaru1404CF
	MTF@ 2.5 lp/mm	>8%	>8%
	Noise, RMS of Dark current	ADU<3	ADU<3
	Cephalometric	Xmaru2301CF	N/A functionality not available
		1210SGA	
		910SGA	
		Xmaru2301CF-O	
Size of Imaging Volume (cm)		Xmaru1404CF : Max. 10x8.5	Xmaru1404CF : Max. 10x8.5
Pixel Resolution	**Computed Tomography**	Xmaru1404CF : - 5.0 lp/mm - 2x2 binning - 2.5 lp/mm - 4x4 binning	Does not support 5.0 lp/mm - 2x2 binning 2.5 lp/mm - 4x4 binning
	Panoramic	Xmaru1404CF : - 5.0 lp/mm - 2x2 binning - 2.5 lp/mm - 4x4 binning	Does not support 5.0 lp/mm - 2x2 binning 2.5 lp/mm - 4x4 binning
	Cephalometric	Xmaru2301CF : 5 lp/mm 1210SGA : 3.9 lp/mm 910SGA : 3.9 lp/mm Xmaru2301CF-O : 5 lp/mm	N/A functionality not available

Descriptive Information		K152106, PaX-i3D Smart (PHT-30LFO) Vatech Co., Ltd.	ProVecta 3D Prime with VistaSoft DÜRR DENTAL SE
Pixel Size	**Computed Tomography**	Xmaru1404CF : - 99 m- 2x2 binning - 198 m- 4x4 binning	Xmaru1404CF : 99 µm - 2x2 binning 198 µm- 4x4 binning
	Panoramic	Xmaru1404CF : - 99 µm- 2x2 binning - 198 µm- 4x4 binning	Xmaru1404CF : 99 µm - 2x2 binning 198 µm- 4x4 binning
	Cephalometric	Xmaru2301CF : 100 x 100 µm	N/A functionality not available
		1210SGA : 127 x 127 µm	
		910SGA : 127 x 127 µm	
		Xmaru2301CF-O : 100 x 100 µm	
Photograph			

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

The two systems share certain common components including the main digital imaging panel and the X-ray tube, Monobloc, MCU, and Power boards. However the mechanical parts as well as the exterior of the device are Dürr Dental developments. The software, while functionally similar, is different, having been derived from our own software cleared in K161444, Trade/Device Name: DBSWIN and VistaEasy Imaging Software. That software required only minor changes in order to recognize the added hardware compatibility of the scanning detector. The key performance difference is that we do not support cephalometric testing.

9. Non-Clinical Data and Performance Testing

Testing to the following IEC and DIN Standards was successfully performed:
IEC 60601-1 Medical Electrical Equipment, Part l: General requirements for basic safety and essential performance
IEC 60601-1-2 Medical Electrical Equipment, Part l-2: General requirements for basic safety and essential performance. Collateral Standard : Electromagnetic Compatibility
IEC 60601-1-3 General Requirements for Radiation Protection in Diagnostic X-Ray Equipment
IEC 60601-1-6 General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-2-63 Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
IEC 60825-1 Safety of laser products - Part 1: Equipment classification and requirements
IEC 62304 Medical Device Software Life-cycle processes
IEC 62366 Medical devices – Application of usability engineering to medical devices
DIN 6868-151 Image quality assurance in diagnostic X-ray departments - Part 151: Acceptance testing of dental radiographic equipment accordance to ROEV - Rules for the inspection of image quality after installation, maintenance and modification
DIN 6868-161 Image Quality Assurance In Diagnostic X-Ray Departments - Part 161: ROEV Acceptance Testing Of Dental Radiographic Equipment For Digital Cone-Beam Computed Tomography
Software and firmware was evaluated in accordance with the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. Risk management activities were documented.
Biocompatibility Assessment:
The Bite Block received the following evaluations:
- Cytotoxicity Testing
- Chemical Analysis Testing
- Biological Safety Testing

The forehead support with cushion received the following evaluation:
- Cytotoxicity testing.

Other patient contact components had already received their own FDA clearances.
Cleaning, Disinfection and Sterilization Testing:
- Bite block manual cleaning and Disinfection Testing was performed.
- Bite block mechanical cleaning and Disinfection Test was performed.
- Bite Block Steam sterilization Test was performed.

Pediatric considerations: Labeling included the recommendations of the FDA Guidance: "*Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff Document issued on November 28, 2017*."
Cybersecurity considerations: Labeling also included cybersecurity strategy information based on FDA's cybersecurity guidance, *"Postmarket Management of Cybersecurity in Medical Devices" dated December 28, 2016.*"

10. Clinical Data: Not required for a finding of substantial equivalence (because the same detector as the predicate is used) but performed to assure diagnostic quality of the dental images. The overall impression is sufficient for dental diagnostics. Good contrast and good resolution. Teeth, osseous structures, sinus maxillaries are clearly shown.

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, DÜRR DENTAL SE concludes that the ProVecta 3D Prime with VistaSoft is substantially equivalent to 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.