DÜRR DENTAL SE
℅ Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

March 5, 2020

Re: K193139
Trade/Device Name: ProVecta 3D Prime Ceph
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: January 27, 2020
Received: January 29, 2020

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/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,

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)*
K193139

Device Name
ProVecta 3D Prime Ceph

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.

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 Ceph

K19 3139

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

1. Date Summary Prepared: 25. October 2019

2. Submitter's Identification:

Submitter's Identification:	**DÜRR DENTAL SE** Höpfigheimer Str. 17 74321 Bietigheim-Bissingen Germany Phone: + 49 (0) 7142 70 5-0 Fax: + 49 (0) 7142 705-500 E-Mail: info@duerr.de www.duerrdental.com	Establishment Registration Name in FURLS: **Duerr DENTAL SE**
Establishment Registration Number:	3015509619	
Submitter's Contact:	Mr. Oliver Lange Director of Quality Management DÜRR DENTAL SE Höpfigheimer Str. 17 74321 Bietigheim-Bissingen, Germany Phone: + 49 (0) 7142 70 5-190 Email: oliver.lange@duerrdental.com	
U.S. Agent & Contact:	Mr. Joseph Latkowski Director of Quality and Regulatory Air Techniques, Inc. 1295 Walt Whitman Road Melville, NY 11747, USA U.S. Phone: 516-214-5574 E-Mail: Joseph.Latkowski@airtechniques.com	

3. Device:

Trade /Proprietary Name:	ProVecta 3D Prime Ceph
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:

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

5. Reference Device:

510(k) Number:	K181432
Manufacturer:	DÜRR DENTAL SE
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
Reason:	This device used K152106 as a predicate but it lacked the CEPH option. With this submission we add the CEPH option.

6. Device Description:

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. This device is similar to our reference device, K181432, but we have now added cephalometric capability, making it entirely equivalent to our predicate device for indications. An option would allow the customer to purchase this new device without the CEPH function, if desired.

7. Indications for use:

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.

8. 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 Ceph**
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 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. SAME, equivalent language.
Image Acquisition Modes	Panoramic, cephalometric and computed tomography	SAME
Imaging Software	EasyDent: 2D viewer and patient management software Ez3D Plus : 3D viewer and image analysis software	VisionX, includes 2D and 3D. Cleared in K192743
Input Voltage	AC 100-240 V	AC 200-240V
Tube Voltage	50-99 kV	60-99 kV
Tube Current	4 ~16 mA	4~16mA
Focal Spot Size	0.5 mm	0,5 mm
Exposure Time	Max. 18 s	Max. 20 s
Slice Width	0.1 mm min.	0.1 mm min.

Descriptive Information		**K152106, PaX-i3D Smart (PHT-30LFO) Vatech Co., Ltd.**	**ProVecta 3D Prime Ceph**
Total Filtration		2.8 mm Al	2.5 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	VisionX
3D Image Viewing Program		Ez3D Plus	VisionX
Anatomical Sites		Maxillofacial	Maxillofacial
Image Receptor	Computed Tomography	Xmaru1404CF	Xmaru1404CF (SAME)
	Panoramic	Xmaru1404CF	Xmaru1404CF (SAME)
	Cephalometric	Xmaru2301CF	Xmaru 2602CF
		1210SGA	
		910SGA	
		Xmaru2301CF-O	
Size of Imaging Volume (cm)		Xmaru1404CF : Max. 10x8.5	Xmaru1404CF: Max. 10x8.5 (SAME)
Pixel Resolution	Computed Tomography	Xmaru1404CF: - 5.0 lp/mm - 2x2 binning - 2.5 lp/mm - 4x4 binning	2.5 lp/mm - 4x4 binning Does not support: 5.0 lp/mm - 2x2 binning
	Panoramic	Xmaru1404CF : - 5.0 lp/mm - 2x2 binning - 2.5 lp/mm - 4x4 binning	2.5 lp/mm - 4x4 binning Does not support: 5.0 lp/mm - 2x2 binning
	Cephalometric	Xmaru2301CF: 5 lp/mm 1210SGA: 3.9 lp/mm 910SGA: 3.9 lp/mm Xmaru2301CF-O: 5 lp/mm	Xmaru 2602CF
Pixel Size Computed	Computed Tomography	Xmaru1404CF : - 99 m- 2x2 binning - 198 m- 4x4 binning	Xmaru1404CF : 99 μm - 2x2 binning 198 μm- 4x4 binning

Descriptive Information		**K152106, PaX-i3D Smart (PHT-30LFO) Vatech Co., Ltd.**	**ProVecta 3D Prime Ceph**
	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	Xmaru 2602CF 200 x 200 μm The predicate uses 2x2 binning, so the resolution is identical.
		1210SGA: 127x127 μm	
		910SGA: 127x127 μm	
		Xmaru2301CF-O: 100x100 μm	
Photograph			

9. Discussion of Similarities and Differences:

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 K190629, Trade/Device Name: DBSWIN and VistaEasy Imaging Software. The key performance difference between this device and our reference clearance K181432 is that we now support cephalometric testing. So BOTH devices, our new one and the predicate, offer identical modalities, including some identical components.

10. Non-Clinical Data and Performance Testing

Testing to the following IEC and DIN Standards was successfully performed:

Standard:	**Standard Title:**
IEC 14971	Medical devices - Application of risk management to medical devices
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

Standard:	Standard Title:
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. Acceptance testing was performed for both the panoramic and cephalometric modes. Line pair and contrast was evaluated using a phantom designed for this purpose.
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:	
Firmware:	The 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: Chin Holder for bite block (Material PBT):	
EN ISO 10993-5	Cytotoxicity
All other accessories have been cleared previously (refer to section 16 - Biocompatibility)	

11. **Clinical Data** Clinical data is not required for a finding of substantial equivalence.

12. **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 Ceph 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.