September 14, 2023

Durr Dental SE
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

Re: K232487
Trade/Device Name: Provecta 3D Prime and 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: August 10, 2023
Received: August 17, 2023

Dear Daniel 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232487

Device Name
ProVecta 3D Prime and ProVecta 3D Prime Ceph

Indications for Use *(Describe)*

ProVecta 3D Prime and ProVecta 3D Prime Ceph are computed tomography x-ray units intended to generate 3D, panoramic and cephalometric (ProVecta 3D Prime Ceph Model) X-ray images in dental radiography for adult and pediatric patients. They provide diagnostic details of the maxillofacial areas for a dental treatment. The devices are 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.

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510(k) Summary, DÜRR DENTAL SE,

ProVecta 3D Prime and ProVecta 3D Prime Ceph, K232487

This 510(k) is being submitted in accordance with the requirements of 21 CFR §807.92.
Date Summary Prepared: September 14, 2023

1. Submitter's Identification: (Below)

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	

2. Device:

Trade /Proprietary Name:	ProVecta 3D Prime and 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

3. Predicate Device:

510(k) Number:	K193139
Manufacturer:	DÜRR DENTAL SE
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. Reference Device: (Software used with the proposed device)

510(k) Number:	K213326
Manufacturer:	DÜRR DENTAL SE
Trade /Proprietary Name:	VisionX 3.0
Device:	Imaging Software
Regulation Description:	Medical image management and processing system
Regulation Medical Specialty:	Radiology
Review Panel:	Radiology
Product Code:	LLZ
Regulation Number:	892.2050
Device Class:	2

5. 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. The ProVecta 3D Prime model does not have the CEPH function.

This premarket notification is because of the revision of the biological evaluation of medical devices documentation according to EN ISO 10993-1:2020. The reason for the revision of the document is the inclusion of the Comfort Bite Foam for the bite block with direct patient contact. The relevant documents regarding biological safety were included and evaluated in this biological evaluation. Furthermore, the Biological Evaluation has been updated to the latest Version of the standard. The name, application and biocompatibility-relevant materials of the rest of the product have not changed

since the last version. In addition to the current bite block (REF: 2210200100), two new, more comfortable variants were developed:
- standard bite block: an optimized version of the existing bite block
- comfort bite block: an extension of the existing bite block
The image management software was recently updated in K213326.

6. Indications for use:
ProVecta 3D Prime and ProVecta 3D Prime Ceph are computed tomography x-ray units intended to generate 3D, panoramic and cephalometric (ProVecta 3D Prime Ceph Model) X-ray images in dental radiography for adult and pediatric patients. They provide diagnostic details of the maxillofacial areas for a dental treatment. The devices are operated and used by physicians, dentists, and x-ray technicians. Not intended for mammography use.

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

Descriptive Information	ProVecta 3D Prime Ceph K193139	ProVecta 3D Prime	ProVecta 3D Prime Ceph
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.	ProVecta 3D Prime and ProVecta 3D Prime Ceph are computed tomography x-ray units intended to generate 3D, panoramic and cephalometric (ProVecta 3D Prime Ceph Model) X-ray images in dental radiography for adult and pediatric patients. They provide diagnostic details of the maxillofacial areas for a dental treatment. The devices are operated and used by physicians, dentists, and x-ray technicians. Not intended for mammography use.	
Image Acquisition Modes	Panoramic, cephalometric, and computed tomography	SAME except without cephalometric	SAME as predicate
Imaging Software	VisionX 3, includes 2D and 3D. Cleared in K192743	VisionX 3.0, includes 2D and 3D, updated in K213326	VisionX 3.0, includes 2D and 3D, updated in K213326
Input Voltage	AC 200-240V	SAME	SAME
Tube Voltage	60-99 kV	SAME	SAME
Tube Current	4~16mA	SAME	SAME
Focal Spot Size	0,5 mm	SAME	SAME
Exposure Time	Max. 20 s	SAME	SAME
Slice Width	0.1 mm min.	SAME	SAME
Total Filtration	2.5 mm Al	SAME	SAME
Chin Rest	Bite block, chin rest and headrest	SAME	SAME
Mechanical	Compact design	SAME	SAME

Descriptive Information		ProVecta 3D Prime Ceph K193139	ProVecta 3D Prime	ProVecta 3D Prime Ceph
Electrical		LDCP logic circuit (Low Dark Current Processing)	SAME	SAME
Software		VistaSoft, DICOM 3.0 compatible	SAME	SAME
2D Image Viewing Program		VisionX	SAME	SAME
3D Image Viewing Program		VisionX	SAME	SAME
Anatomical Sites		Maxillofacial	SAME	SAME
Image Receptor	Computed Tomography	Xmaru1404CF	SAME	SAME
	Panoramic	Xmaru1404CF	SAME	SAME
	Cephalometric	Xmaru 2602CF	N/A	SAME
Size of Imaging Volume (cm)		Xmaru1404CF: Max. 10x8.5	SAME	SAME
Pixel Resolution	Computed Tomography	2.5 lp/mm - 4x4 binning Does not support: 5.0 lp/mm - 2x2 binning	SAME	SAME
	Panoramic	2.5 lp/mm - 4x4 binning Does not support: 5.0 lp/mm - 2x2 binning	SAME	SAME
	Cephalometric	Xmaru 2602CF	N/A	SAME
Pixel Size Computed	Computed Tomography	Xmaru1404CF : 99 μm - 2x2 binning 198 μm- 4x4 binning	SAME	SAME
	Panoramic	Xmaru1404CF : 99 μm - 2x2 binning 198 μm- 4x4 binning	SAME	SAME
	Cephalometric	Xmaru 2602CF 200 x 200 μm	N/A	SAME as Predicate

Descriptive Information	ProVecta 3D Prime Ceph K193139	ProVecta 3D Prime	ProVecta 3D Prime Ceph
Photograph		 Without CEPH Arm.	 Identical appearance, no change.

8. Discussion of Similarities and Differences:
This premarket notification is specifically for a change in the bite-block material. Because of the change in material, biocompatibility issues had to be addressed.

9. Non-Clinical Data and Performance Testing (New Bite Foam)
Cytotoxicity, L 929-Proliferation, EN ISO 10993-1, -5, -12. Result: Not cytotoxic.

The following new documents have been added to our technical file:
Test Report Chemical Analysis Comfort Bite Foam
Test Report Cytotoxicity Comfort Bite Foam
Test Report Cytotoxicity Packaging Comfort Bite Foam
Test Report Bite Block Manufacturer Report Cytotoxicity-
Datasheet, O.C.-PE RG 45 KB-D-No 5607267
Safety Information

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

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 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.