December 23, 2025

OrangeCAD Med GmbH
℅ Chris Brown
Manager
Aclivi, LLC
3250 Brackley Drive
Ann Arbor, Michigan 48105

Re: K253312
Trade/Device Name: OrangeCAD Med Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 30, 2025
Received: September 30, 2025

Dear Chris Brown:

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,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
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)*

Device Name
OrangeCAD Med Abutments

Indications for Use *(Describe)*
OrangeCAD Med Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.

OrangeCAD Med Abutments are compatible with the following dental implant system:

Compatibility Table

Compatible Implant Systems	Series	Implant Body Diameter mm	Implant Platform Diameter mm (name)
Straumann Bone Level	SM-BL	3.3 4.1, 4.8	3.1 (NC) 3.7, 4.4 (RC)

Type of Use *(Select one or both, as applicable)*

[X] 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
K253312
OrangeCAD Med Abutments
December 23, 2025

ADMINISTRATIVE INFORMATION

Manufacturer Name: OrangeCAD Med GmbH
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Karlsruhe 76131 Germany
Telephone: +49 721 986 1880
Fax: n/a

Official Contact: Dr. Markus Munz, Regulatory Affairs
Email: m.munz@orangecad-med.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	OrangeCAD Med Abutments
Common Name:	Abutment, Implant, Dental, Endosseous
Regulation Name:	Endosseous dental implant abutment
Regulation Number:	21 CFR 872.3630
Device Class:	Class II
Product Code:	NHA
Review Panel:	Dental Products Panel
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

PREDICATE DEVICE INFORMATION

The devices within this submission are substantially equivalent in indications, intended use and technological characteristics to the following Predicate device. The Subject device shares technological characteristics with the following Reference devices.

510(k)	Predicate Device Name	Company Name
K170588	DESS Dental Smart Solutions	Terrats Medical SL
510(k)	**Reference Device Name**	**Company Name**
K191123	Medentika Multi-unit Abutments	Medentika GmbH
K140878	Straumann Bone Level Tapered Implant	Straumann USA, LLC.

INDICATIONS FOR USE

OrangeCAD Med Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.

OrangeCAD Med Abutments are compatible with the following dental implant system:

Compatibility Table

Compatible Implant Systems	Series	Implant Body Diameter mm	Implant Platform Diameter mm (name)
Straumann Bone Level	SM-BL	3.3 4.1, 4.8	3.1 (NC) 3.7, 4.4 (RC)

DEVICE DESCRIPTION

The Subject device OrangeCAD Med Abutments is a dental implant abutment system that includes two abutment designs. The abutment designs are Straight Multi-Unit Abutments and Healing Abutments. Straight Multi-unit abutments include prosthetic level restorative components. The Subject device abutments are compatible with Straumann Bone Level implants. The compatible implant body diameters range from 3.3 to 4.8 mm, with prosthetic platform diameters that range from 3.1 (NC) to 4.4 mm (RC).

Healing abutments are intended to be used with individual endosseous dental implants. They are considered one-part abutments. The base portion of the healing abutment has a non-indexed connection and is connected directly to the implant with an integral screw.

Multi-Unit Abutments (MUAs) are intended for use with multi-unit restorations. They are considered two-part abutments. The base portion of the Straight MUA has a non-indexed connection and is connected directly to the implant with an integral screw. The second part of the MUA is a mating coping or healing cap which is retained with a prosthetic screw.

All Subject device abutments and prosthetic components are pre-manufactured from Ti-6Al-4V ELI (Grade 23) titanium conforming to ASTM F136, *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)* and are provided non-sterile to the user.

The following table shows the Subject device abutments for the Straumann Bone Level compatible implant platforms.

Compatible Implant System	Implant Diameter (mm)	Implant Platform Diameter (mm)	Implant/ abutment Connection Diameter (mm)	Subject Device Abutment Designs		
				Healing Abutment (non-indexed)	Straight Multi-Unit (non-indexed)	Screws
Straumann Bone Level	3.3	3.1 (NC)	2.8 (NC)	X	X	X
	4.1	3.7 (RC)	3.3 (RC)	X	X	X
	4.8	4.1 (RC)	3.3 (RC)	X	X	X
Material				**Grade 23 – Titanium Ti-4Al-6V-ELI**		
Finish				None		

All Subject device abutments are provided in a straight design with no angulation and are intended for implants placed in a straight/vertical position without angulation.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included:

A reverse engineering study of OEM implant bodies, OEM abutments, and OEM abutment screws was performed to demonstrate compatibility with the Straumann Bone Level implant system (K140878).

Biocompatibility cytotoxicity testing to ISO 10993-5 was performed on worst-case abutment constructs.

Sterilization validation testing to ISO 17665-1 and ISO 14937 was performed on worst-case abutment constructs.

A non-clinical worst-case MRI review was performed to evaluate the Subject device in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795). This MRI review was leveraged for the Subject device.

No clinical or animal testing data is included in this premarket notification.

EQUIVALENCE TO MARKETED DEVICE

The Subject device is substantially equivalent in Indications for Use, Technological Characteristics, and design principles to Predicate device listed above and additionally incorporates technology of the Reference devices. The Summary tables at the end of this section compare the Subject, Predicate and the Reference devices.

Indications for Use

The differences between the Subject device and the K170588 Predicate device IFUS are primarily related to the specific device names and compatible implant lines. Since the K170588 Predicate device includes additional abutment designs, there is additional language included in the IFUS specific to those abutment designs. This language is not needed or required for multi-unit abutment designs, so it is not included in the Subject device IFUS. These minor differences do not impact substantial equivalence because the IFUSs express the same intended use to facilitate dental prosthetic restorations.
The Indications for Use Statement (IFUS) of the Subject device is highly similar to the K191123 Predicate Reference device. The IFUSs differ only in the name(s) and sizes of the compatible implant systems. These minor differences do not impact substantial equivalence because the IFUSs express the same intended use to facilitate dental prosthetic restorations.
The IFUS of the Subject device is similar to the K140878 Reference device in that both devices are intended to be used to facilitate functional and esthetic rehabilitation of the upper and lower jaw. The wording of the K140878 Reference device is focused on the implant portion of the rehabilitation. But this difference does not impact substantial equivalence because the IFUSs express the same intended use to facilitate dental prosthetic restorations, expressed equivalently using different specific wording.

Technological Characteristics

The Subject, K170588 Predicate and K191123 Reference devices have the same product code/regulation. They are all fabricated from the same titanium alloy. They all share the same nature of an internal implant connection, all offering non-engaging connections.

The Subject device's multi-unit abutment technological characteristics are highly similar to the K191123 Reference device with the only differences being the compatible implant systems and abutment dimensions specific to those implant systems. The K191123 Reference device additionally offers angled multi-unit abutment design configuration as opposed to the Subject device straight configuration. The Subject and K191123 Reference device both support both cement-retained or screw-retained prosthetic restorations both in multi-unit (Multi-Unit Abutment) configurations.

The Subject and K170588 Predicate device both support both in single unit (healing abutment) and cement-retained or screw-retained prosthetic restorations both in multi-unit (Multi-Unit Abutment) configurations.

The Subject, K170588 Predicate and K191123 Reference devices share the same end-user Steam Sterilization method, biocompatibility and MR Safety classification.

The K170588 Predicate and K191123 Reference devices are leveraged for support of substantial equivalence with respect to the Straumann Bone Level implant system implant diameters, implant/abutment connection interface, platform diameter and abutment gingival height dimensions. The K140878 Reference device is also included in support of the implant/abutment connection interface.

The Subject device offers a slightly lower gingival height (0.5 mm) for Multi-Unit Abutments than the K170588 Predicate device (1.5 mm – based on K170588 device labeling). However, the 0.5 mm gingival height is supported through other K170588 abutment designs (titanium base and titanium blanks) for the same implant diameters based on K170588 device labeling. The single unit abutment designs of the K170588 Predicate device represent a worst-case scenario relative to the Subject device multi-unit abutments which are intended to support multi-unit prosthetic devices with loads distributed over multiple implants and abutments.

Reverse engineering and compatibility analysis was performed to validate physical compatibility with the Straumann Bone Level implant connection.

Minor differences in the prosthetic platform diameter dimensions and compatible implant systems between the Subject and Predicate device do not affect substantial equivalence. These minor differences do not impact safety or effectiveness as these differences are related to the compatible OEM implant designs.

CONCLUSION

Overall, the Indications for Use statements of the Subject and Predicate devices are highly similar, differing only in the list of compatible implant system systems.

Overall, the Technological Characteristics, mode of operation and materials of the Subject device are substantially equivalent to that of the Predicate device, including technological characteristics from the Reference devices.

The basis for the belief that the Subject device is substantially equivalent to the sponsor's Predicate and Reference devices and is summarized in the following comparison tables.

Table A – Comparison of Indications for Use Statement

<table>
<tr>
<td>Subject Device
OrangeCAD Med Abutments
OrangeCAD Med GmbH</td>
<td>Predicate Device
DESS Dental Smart Solutions
Terrats Medical SL
K170588</td>
<td>Reference Device
Medentika Multi-unit Abutments
Medentika GmbH
K191123</td>
<td>Reference Device
Straumann Bone Level Tapered Implant
Straumann USA, LLC.
K140878</td>
</tr>
<tr>
<td>OrangeCAD Med Abutments are intended for use with endosseous dental implants in the maxilla or mandible to provide support for prosthetic restorations.

OrangeCAD Med Abutments are compatible with the following dental implant system:
Compatibility Table
<table>
<tr><th>Compatible Implant Systems</th><th>Series</th><th>Implant Body Diameter mm</th><th>Implant Platform Diameter mm (name)</th></tr>
<tr><td>Straumann Bone Level</td><td>SM-BL</td><td>3.3
4.1, 4.8</td><td>3.1 (NC)
3.7, 4.4 (RC)</td></tr>
</table>
</td>
<td>DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.

All digitally designed custom abutments for use with TiBase or Pre-milled Blank are to be sent to a Terrats Medical validated milling center for manufacture.

Compatible Implant Systems
<table>
<tr><th>Implant System Compatibility</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>3i Certain®</td><td>3.25, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>3i OSSEOTITE®</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>OsseoSpeed™</td><td>3.5, 4.0, 5.0</td><td>3.5/4.0, 4.5/5.0</td></tr>
<tr><td>FRIADENT XiVE</td><td>3.4, 3.8, 4.5</td><td>3.4, 3.8, 4.5</td></tr>
<tr><td>NobelActive®</td><td>3.5, 4.3, 5.0</td><td>NP, RP</td></tr>
<tr><td>NobelReplace Conical</td><td>3.5, 4.3, 5.0</td><td>NP, RP</td></tr>
<tr><td>Nobel Replace Trilobe</td><td>3.5, 4.3, 5.0</td><td>NP, RP, WP</td></tr>
<tr><td>Brånemark</td><td>3.5, 3.75/4.0, 5.0</td><td>NP, RP, WP</td></tr>
<tr><td>Straumann® Bone Level</td><td>3.3, 4.1, 4.8</td><td>NC, RC</td></tr>
<tr><td>Straumann® Tissue Level</td><td>3.3, 4.1, 4.8</td><td>RN, WN</td></tr>
<tr><td>Zimmer Tapered Screw Vent</td><td>3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr>
</table>
</td>
<td>Multi-unit abutments are indicated for use with dental implants as a support for multi-unit screw retained bridges and bars in the maxilla or mandible of a partially or fully edentulous patient.

Multi-unit Abutments are used for the restoration of the following dental implant systems:
<table>
<tr><th>Medentika series</th><th>Implant System</th><th>Implant Diameter</th><th>Platform Diameter</th></tr>
<tr><td>EV-Series</td><td>Dentsply® Implants - ASTRA TECH OsseoSpeed®</td><td>3.6, 4.2, 4.8</td><td>3.6, 4.2, 4.8</td></tr>
<tr><td>F-Series</td><td>Nobel Biocare NobelActive - NobelReplace Conical</td><td>3.5, 4.3, 5.0</td><td>NP 3.5, RP 4.3/5.0</td></tr>
<tr><td>H-Series</td><td>Biomet 3i - Certain</td><td>3.25, 4.0</td><td>3.4, 4.1</td></tr>
<tr><td>L-Series</td><td>Straumann - Bone Level</td><td>3.3, 4.1, 4.8</td><td>3.3, 4.1, 4.8</td></tr>
<tr><td>N-Series</td><td>Straumann - Soft Tissue Level</td><td>4.1, 4.8</td><td>4.8, 6.5</td></tr>
<tr><td>R-Series</td><td>Zimmer Dental Tapered Screw-vent</td><td>3.3, 3.7, 4.1, 4.7</td><td>3.5, 4.5</td></tr>
</table>
</td>
<td>Straumann ® dental implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments)</td>
</tr>
</table>

Table B - Comparison of Technological Characteristics

Topic	**Subject Device** OrangeCAD Med Abutments OrangeCAD Med GmbH	**Predicate Device** DESS Dental Smart Solutions Terrats Medical SL K170588	**Reference Device** Medentika Multi-unit Abutments Medentika GmbH K191123	**Reference Device** Straumann Bone Level Tapered Implant Straumann USA, LLC. K140878
Intended Use	Functional and esthetic prosthetic rehabilitation of the edentulous or semi-edentulous maxilla and mandible.	Functional and esthetic prosthetic rehabilitation of the edentulous or semi-edentulous maxilla and mandible.	Functional and esthetic prosthetic rehabilitation of the edentulous or semi-edentulous maxilla and mandible.	Functional and esthetic rehabilitation of the edentulous maxilla and mandible
Reason for Predicate/Reference	Not Applicable	Indications for Use Statement, Implant compatibility, abutment design, materials	Material, sterilization, biocompatibility, abutment design, engaging and non-engaging connection	Implants, Implant/Restorative interface
Product Code	NHA	NHA	NHA	DZE
Regulation	872.3630	872.3630	872.3630	872.3640
Abutment Design	**Healing Abutments** Material: Ti-6AL-4V ELI Alloy (Abutment and Screw) conforming to ASTM F136 Gingival Height: 3 to 5 mm Implant Platform Diameter: 3.1 to 4.4 mm Prosthetic Diameter: 4.5, 4.9 mm Abutment Angle: Straight (0°)	**Healing Abutments** Material: Ti-6AL-4V Alloy (Abutment and Screw) Gingival Height: 0.8 to 5.0 mm* 3.0 to 5.0 mm (Straumann BL)** Implant Platform Diameter: 3.1 - 6.0 mm* 3.1 – 4.4 mm (Straumann BL)** Prosthetic Diameter: n/a Abutment Angle: Straight (0°)	n/a	n/a
	Multi-Unit Abutment Straight Material: Ti-6AL-4V ELI Alloy (Abutment and Screw) conforming to ASTM F136 Gingival Height 0.5 to 4.5 mm Implant Platform Diameter: 3.1 to 4.4 mm Prosthetic Diameter: 4.8 mm Abutment Angle: Straight (0°)	**Multi-Unit Abutment Straight** Material: Ti-6AL-4V Alloy (Abutment and Screw) Gingival Height: 0.5 to 5.0 mm*** 3.0 to 5.0 mm (Straumann BL)** Implant Platform Diameter: 3.1 - 6.0 mm* 3.1 – 4.4 mm (Straumann BL) Prosthetic Diameter: 4.8 mm Abutment Angle: Straight (0°)	**Multi-Unit Abutment Straight** Material: Ti-6AL-4V Alloy conforming to ASTM F136 (Abutment and Screw) Gingival Height: GH 0.6 to GH 5.5 mm* Implant Platform Diameter: 3.1 to 6.5 mm* 3.1 – 4.4 mm (Straumann BL) Prosthetic Diameter: 4.8 mm Abutment Angle: Straight (0°)	n/a
Abutment/Implant Interface	Internal connection, non-engaging	Internal connection, engaging and non-engaging	Internal connection, engaging and non-engaging	Internal connection
Prosthesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained
Restoration	Single unit (Healing Abutments) Multi-unit (Multi-Unit Abutments)	Single unit Multi-unit	Multi-unit	Single unit Multi-unit
Sterilization - Abutment	Steam Sterilization– End-User	Steam Sterilization– End-User	Steam Sterilization– End-User	n/a