

K253312 OrangeCAD Med AbutmentsDec 23, 2025
84 days to decisionK253312 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k253312/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Sep 30, 2025
Decision date	Dec 23, 2025
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orangecad Med GmbH
Location	Karlsruhe, DE
Contact	Markus Munz
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Aclivi, LLC
Contact	Chris Brown

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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