

K253341 Custom Abutments ASDec 23, 2025
84 days to decisionK253341 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k253341/>**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	Medentika GmbH
Location	San Diego, CA, US
Contact	Alexandra Schulz
510(k) history	10 submissions · 10 cleared · 2015-2025

REGULATORY CONSULTANT

Consulting firm	Straumann USA, LLC
Contact	Jennifer Jackson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253341/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026