FDA 510(k) Premarket Notification

# K253341 Custom Abutments AS

**CLEARED**

Dec 23, 2025
84 days to decision

K253341 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k253341/

## SUBMISSION DETAILS

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|---|---|
| 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

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|---|---|
| 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