FDA 510(k) Premarket Notification

CLEARED

K223113 Medentika Abutment System, Medentika CAD/CAM Abutments, Medentika CAD/CAM TiBases, Medentika Multi-unit Abutments

Apr 15, 2024
560 days to decision

K223113 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k223113/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Oct 3, 2022
Decision date	Apr 15, 2024
Days to decision	560 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 M Jackson

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