FDA 510(k) Premarket Notification

K251294 Bonafix Implant Abutments

CLEARED

Oct 15, 2025
173 days to decision

K251294 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k251294/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Apr 25, 2025
Decision date	Oct 15, 2025
Days to decision	173 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zentek Medical, LLC**
Location	Manalapan, NJ, US
Contact	Michael Vinnik
510(k) history	3 submissions · 3 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	**Compliance4Devices**
Contact	Carlos Marín

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