

**K251294 Bonafix Implant Abutments**Oct 15, 2025  
173 days to decisionK251294 · Product code: **NHA** · Dental  
Source: <https://www.510kdatabase.net/k251294/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Compliance4Devices</b>
Contact	Carlos Marín

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

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