

K221673 Bonafix TiBaseJul 14, 2023
400 days to decisionK221673 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k221673/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jun 9, 2022
Decision date	Jul 14, 2023
Days to decision	400 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	Juan Tezak

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221673/> 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 26, 2026