

K213677 Bonafix 2 PlusDec 20, 2022
393 days to decisionK213677 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k213677/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Nov 22, 2021
Decision date	Dec 20, 2022
Days to decision	393 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213677/> 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