FDA 510(k) Premarket Notification

K221673 Bonafix TiBase

CLEARED

Jul 14, 2023
400 days to decision

K221673 · 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