FDA 510(k) Premarket Notification

K213677 Bonafix 2 Plus

CLEARED

Dec 20, 2022
393 days to decision

K213677 · 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