

K232049 IS-III active Short ImplantMar 28, 2024
262 days to decisionK232049 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k232049/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jul 10, 2023
Decision date	Mar 28, 2024
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neobiotech Co., Ltd.
Location	Santa Fe Springs, CA, US
Contact	Young-Ku Heo
510(k) history	17 submissions · 17 cleared · 2004-2024

REGULATORY CONSULTANT

Consulting firm	Withus Group, Inc.
Contact	April Lee

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/k232049/> 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 13, 2026