

K253334 ZENEX Implant System_Short (R-System)Mar 16, 2026
167 days to decisionK253334 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k253334/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 30, 2025
Decision date	Mar 16, 2026
Days to decision	167 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Izenimplant Co., Ltd.
Location	Pyeongtaek-Si, KR
Contact	Kim Nayoung
510(k) history	8 submissions · 8 cleared · 2022-2026

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

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