

K211090 ZENEX Implant SystemApr 13, 2022
366 days to decisionK211090 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k211090/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Apr 12, 2021
Decision date	Apr 13, 2022
Days to decision	366 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	KMC, Inc.
Contact	Milly Milly

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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