

K241127 INNO SLA Mini Plus® Implant SystemDec 27, 2024
248 days to decisionK241127 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k241127/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Apr 23, 2024
Decision date	Dec 27, 2024
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cowellmedi Co., Ltd.
Location	Newington, NH, US
Contact	Donghyung Lee
510(k) history	14 submissions · 14 cleared · 2004-2025

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

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

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