

K231426 8plant Implant SystemMay 24, 2024
373 days to decisionK231426 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k231426/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	May 17, 2023
Decision date	May 24, 2024
Days to decision	373 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hoowon Edi Co., Ltd.
Location	Gimhae, KR
Contact	Jihun Choi
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Wise Company, Inc.
Contact	Sanglok Lee

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

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