

K211812 BLUEDIAMOND IMPLANT, Abutment ScrewJan 6, 2023
574 days to decisionK211812 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k211812/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jun 11, 2021
Decision date	Jan 6, 2023
Days to decision	574 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Megagen Implant Co., Ltd.
Location	Santa Fe Springs, CA, US
Contact	Hyo Eun Lee
510(k) history	31 submissions · 31 cleared · 2008-2025

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