

**K241972 BLUEDIAMOND IMPLANT**Dec 27, 2024  
175 days to decisionK241972 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k241972/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jul 5, 2024
Decision date	Dec 27, 2024
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241972/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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