

**K230618 MegaGen Dental Implant Systems Portfolio - MR  
Conditional**Oct 11, 2023  
219 days to decisionK230618 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k230618/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Mar 6, 2023
Decision date	Oct 11, 2023
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Megagen Implant Co., Ltd.</b>
Location	Santa Fe Springs, CA, US
Contact	Hyejin Jung
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/k230618/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026