

**K240754 N2**Mar 21, 2024  
1 days to decisionK240754 · Product code: **EIA** · Dental  
Source: <https://www.510kdatabase.net/k240754/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Operative Dental (EIA)
Date received	Mar 20, 2024
Decision date	Mar 21, 2024
Days to decision	1 days
Third-party review	Yes
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	Lee Hyo-Eun
510(k) history	31 submissions · 31 cleared · 2008-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Third Party Review Group, LLC</b>
Contact	Dave Yungvirt

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

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