

**K131289 I-GEN**Sep 25, 2013  
142 days to decisionK131289 · Product code: **JEY** · DentalSource: <https://www.510kdatabase.net/k131289/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	May 6, 2013
Decision date	Sep 25, 2013
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Megagen Implant Co., Ltd.</b>
Location	Santa Fe Springs, CA, US
Contact	APRIL 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/k131289/> 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 June 8, 2026