

**K142813 Biogenesis Implant System-Kisses**Jul 31, 2015  
305 days to decisionK142813 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k142813/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 29, 2014
Decision date	Jul 31, 2015
Days to decision	305 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biogenesis Co., Ltd.</b>
Location	Anaheim, CA, US
Contact	Haeyong Lee
510(k) history	2 submissions · 2 cleared · 2013-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k142813/> 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 4, 2026