

**K192197 Magicore II System**Apr 28, 2020  
259 days to decisionK192197 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k192197/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Aug 13, 2019
Decision date	Apr 28, 2020
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Innobiosurg Co., Ltd.</b>
Location	Echo, AZ, US
Contact	Eun-Ji Yoo
510(k) history	15 submissions · 15 cleared · 2015-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192197/> 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 26, 2026