

**K212517 Magicore System**Oct 15, 2021  
66 days to decisionK212517 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k212517/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Aug 10, 2021
Decision date	Oct 15, 2021
Days to decision	66 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Withus Group, Inc.</b>
Contact	April Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212517/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026