

K220517 IBS SystemDec 20, 2022
300 days to decisionK220517 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k220517/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Feb 23, 2022
Decision date	Dec 20, 2022
Days to decision	300 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Innobiosurg Co., Ltd.
Location	Echo, AZ, US
Contact	Ga Yun Kim
510(k) history	15 submissions · 15 cleared · 2015-2022

REGULATORY CONSULTANT

Consulting firm	Withus Group, Inc.
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)

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