FDA 510(k) Premarket Notification

K212517 Magicore System

CLEARED

Oct 15, 2021
66 days to decision

K212517 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k212517/

SUBMISSION DETAILS

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

Company	**Innobiosurg Co., Ltd.**
Location	Echo, AZ, US
Contact	JongHyuk Seo
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