

K210523 ImplanovaSep 30, 2021
219 days to decisionK210523 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k210523/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Feb 23, 2021
Decision date	Sep 30, 2021
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Dental Evolutions, Inc.
Location	Beverly Hills, CA, US
Contact	Matthew Mineros
510(k) history	2 submissions · 2 cleared · 2015-2021

REGULATORY CONSULTANT

Consulting firm	Arazy Group
Contact	Raymond Kelly

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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