

K180968 AlphaDent Implants Dental Implants SystemJul 3, 2019
446 days to decisionK180968 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k180968/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Apr 13, 2018
Decision date	Jul 3, 2019
Days to decision	446 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Alphadent Implants, Ltd.
Location	Leonberg-Gebershein, DE
Contact	Natalia Kenig
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Qualitech Top , Ltd.
Contact	Simha Sibony

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

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