

K182143 ALFA GATE Dental Implants SystemOct 3, 2019
422 days to decisionK182143 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k182143/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Aug 7, 2018
Decision date	Oct 3, 2019
Days to decision	422 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Alfa Gate Mazen, Ltd.
Location	Kfar Qara, IL
Contact	Mohamad Zahalka
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Sterling Medical Registration
Contact	Daniela Levy

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182143/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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