

K182219 SGS Dental Implants SystemAug 29, 2019
379 days to decisionK182219 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k182219/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Aug 15, 2018
Decision date	Aug 29, 2019
Days to decision	379 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sgs International, Ltd.
Location	Woodland Hills, CA, US
Contact	Michaeli Shabtai
510(k) history	2 submissions · 2 cleared · 2014-2019

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](https://accessdata.fda.gov)

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