

K181854 OssBuilder SystemMay 7, 2019
300 days to decisionK181854 · Product code: **DZL** · Dental
Source: <https://www.510kdatabase.net/k181854/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Intraosseous (DZL)
Date received	Jul 11, 2018
Decision date	May 7, 2019
Days to decision	300 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Osstem Implant Co., Ltd.
Location	Busan, KR
Contact	Jungmin Yoo
Website	https://www.osstem.com
510(k) history	68 submissions · 68 cleared · 2006-2026

REGULATORY CONSULTANT

Consulting firm	Hiossen, Inc.
Contact	Peter Lee

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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