

K192347 ST Internal Implant SystemNov 14, 2019
77 days to decisionK192347 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k192347/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Aug 29, 2019
Decision date	Nov 14, 2019
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Megagen Implant Co., Ltd.
Location	Santa Fe Springs, CA, US
Contact	You Jung Kim
510(k) history	31 submissions · 31 cleared · 2008-2025

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