

K191127 Advanced Intermezzo Implant SystemOct 8, 2019
162 days to decisionK191127 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k191127/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Apr 29, 2019
Decision date	Oct 8, 2019
Days to decision	162 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	JiYoung Son
510(k) history	31 submissions · 31 cleared · 2008-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191127/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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