

**K250280 SD TL Implant System**Jul 23, 2025  
173 days to decisionK250280 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k250280/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jan 31, 2025
Decision date	Jul 23, 2025
Days to decision	173 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Arum Dentistry Co., Ltd.</b>
Location	Yuseong-Gu, Daejeon, KR
Contact	Choi Won-Yi
510(k) history	17 submissions · 17 cleared · 2020-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250280/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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