

**K163557 SS SA Fixture**May 15, 2017  
147 days to decisionK163557 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k163557/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Dec 19, 2016
Decision date	May 15, 2017
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Osstem Implant Co., Ltd.</b>
Location	Busan, KR
Contact	Mr. HeeKwon
Website	<a href="https://www.osstem.com">https://www.osstem.com</a>
510(k) history	68 submissions · 68 cleared · 2006-2026

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163557/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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