

**K172354 OssBuilder System**Mar 26, 2018  
235 days to decisionK172354 · Product code: **JEY** · DentalSource: <https://www.510kdatabase.net/k172354/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Aug 3, 2017
Decision date	Mar 26, 2018
Days to decision	235 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Osstem Implant Co., Ltd.</b>
Location	Busan, KR
Contact	Jungmin Yoo
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/k172354/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 30, 2026