

K120951 SMARTBUILDER SYSTEMOct 3, 2012
187 days to decisionK120951 · Product code: **JEY** · DentalSource: <https://www.510kdatabase.net/k120951/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Mar 30, 2012
Decision date	Oct 3, 2012
Days to decision	187 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osstem Implant Co., Ltd.
Location	Busan, KR
Contact	PATRICK LIM
Website	https://www.osstem.com
510(k) history	68 submissions · 68 cleared · 2006-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120951/> Data sourced from FDA 510(k) public records (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. - Generated June 13, 2026