

K130840 SMARTBUILDER SYSTEM (SB1)Sep 18, 2013
175 days to decisionK130840 · Product code: **JEY** · DentalSource: <https://www.510kdatabase.net/k130840/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Mar 27, 2013
Decision date	Sep 18, 2013
Days to decision	175 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

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