

K161103 US SA Implant SystemFeb 2, 2017
289 days to decisionK161103 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k161103/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Apr 19, 2016
Decision date	Feb 2, 2017
Days to decision	289 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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