

K161604 OSSTEM Implant SystemOct 17, 2016
129 days to decisionK161604 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k161604/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jun 10, 2016
Decision date	Oct 17, 2016
Days to decision	129 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161604/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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