

K161197 Orthodontic ScrewDec 21, 2016
237 days to decisionK161197 · Product code: **OAT** · Dental
Source: <https://www.510kdatabase.net/k161197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Orthodontic (OAT)
Date received	Apr 28, 2016
Decision date	Dec 21, 2016
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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