

K183475 T1-CS, T1-CAug 30, 2019
256 days to decisionK183475 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k183475/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Dec 17, 2018
Decision date	Aug 30, 2019
Days to decision	256 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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