

K183347 K3Sep 4, 2019
275 days to decisionK183347 · Product code: **EIA** · DentalSource: <https://www.510kdatabase.net/k183347/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Dec 3, 2018
Decision date	Sep 4, 2019
Days to decision	275 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Hiossen, Inc.
Contact	Peter Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183347/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026