

K182091 Osstem Abutment SystemJul 12, 2019
343 days to decisionK182091 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k182091/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Aug 3, 2018
Decision date	Jul 12, 2019
Days to decision	343 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Osstem Implant Co., Ltd.
Location	Busan, KR
Contact	Jungmin Yoo
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)

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Device record: <https://www.510kdatabase.net/k182091/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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