

**K221684 Osstem Abutment System**Sep 8, 2022  
90 days to decisionK221684 · Product code: **NHA** · Dental  
Source: <https://www.510kdatabase.net/k221684/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jun 10, 2022
Decision date	Sep 8, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Osstem Implant Co., Ltd.</b>
Location	Busan, KR
Contact	Seungju Kang
Website	<a href="https://www.osstem.com">https://www.osstem.com</a>
510(k) history	68 submissions · 68 cleared · 2006-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hiossen, Inc.</b>
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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