

K233805 K5Sep 3, 2024
279 days to decisionK233805 · Product code: **EIA** · Dental
Source: <https://www.510kdatabase.net/k233805/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Nov 29, 2023
Decision date	Sep 3, 2024
Days to decision	279 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Osstem Implant Co., Ltd. Chair Business
Location	Ansan-Si, KR
Contact	Sangyong Lee
510(k) history	1 submissions · 1 cleared · 2024-2024

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

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