

K251491 K5 Cart, K5 Mount, K5 SwingJul 17, 2025
64 days to decisionK251491 · Product code: **EIA** · DentalSource: <https://www.510kdatabase.net/k251491/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Operative Dental (EIA)
Date received	May 14, 2025
Decision date	Jul 17, 2025
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Osstem Implant Company., Ltd. Chair Business
Location	Ansan-Si, KR
Contact	Jimin Hyun
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Hiossen, Inc.
Contact	Leszczak Mateusz

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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