FDA 510(k) Premarket Notification

K251569 Bone Screw

CLEARED

Aug 13, 2025
83 days to decision

K251569 · Product code: **DZL** · Dental
Source: https://www.510kdatabase.net/k251569/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Intraosseous (DZL)
Date received	May 22, 2025
Decision date	Aug 13, 2025
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Hiossen, Inc.**
Contact	Mateusz Leszczak

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