FDA 510(k) Premarket Notification

K232012 N1

CLEARED

Nov 28, 2023
145 days to decision

K232012 · Product code: **EHD** · Radiology
Source: https://www.510kdatabase.net/k232012/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Jul 6, 2023
Decision date	Nov 28, 2023
Days to decision	145 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Osstem Implant Co., Ltd.**
Location	Busan, KR
Contact	Jimin Hyun
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