

**K232012 N1**Nov 28, 2023  
145 days to decisionK232012 · Product code: **EHD** · Radiology  
Source: <https://www.510kdatabase.net/k232012/>**SUBMISSION DETAILS**

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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**

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Company	<b>Osstem Implant Co., Ltd.</b>
Location	Busan, KR
Contact	Jimin Hyun
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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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232012/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026