

**K243469 SIGNEX**May 29, 2025  
202 days to decisionK243469 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k243469/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Nov 8, 2024
Decision date	May 29, 2025
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Osteonic Co., Ltd.</b>
Location	Seoul, KR
Contact	Hye-Min Ahn
Website	<a href="https://www.osteonic.com">https://www.osteonic.com</a>
510(k) history	20 submissions · 20 cleared · 2015-2026

Osteonic Co., Ltd. is a Seoul-based medical device manufacturer specializing in bone implant and reconstructive implant systems. The company designs metal and biodegradable composite-based products for surgical applications. Osteonic has received FDA 510(k) clearances from total submissions since 2015. The company's cleared devices span orthopedic, neurology, and dental categories. Most recent clearance occurred in 2026, confirming active regulatory engagement and current market presence. The company's product portfolio includes orthopedic plating systems, neuro plating s...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Wise Company, Inc.</b>
Contact	Sanglok 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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