

**K254182 Aster**Feb 26, 2026  
65 days to decisionK254182 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k254182/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Dec 23, 2025
Decision date	Feb 26, 2026
Days to decision	65 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	Jisun Lee
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...