

**K160363 OPTIMUS CMF SYSTEM**Oct 20, 2016  
254 days to decisionK160363 · Product code: **JEY** · Dental  
Source: <https://www.510kdatabase.net/k160363/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Bone (JEY)
Date received	Feb 9, 2016
Decision date	Oct 20, 2016
Days to decision	254 days
Third-party review	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...

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