

K140037 OPTIMUS CMF SYSTEMJan 20, 2015
378 days to decisionK140037 · Product code: **JEY** · Dental
Source: <https://www.510kdatabase.net/k140037/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Jan 7, 2014
Decision date	Jan 20, 2015
Days to decision	378 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osteonic Co., Ltd.
Location	Seoul, KR
Contact	Priscilla Chung
Website	https://www.osteonic.com
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...
