

K141911 OPTIMUS NEURO SYSTEMFeb 10, 2015
210 days to decisionK141911 · Product code: **GWO** · Neurology
Source: <https://www.510kdatabase.net/k141911/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Alterable (GWO)
Date received	Jul 15, 2014
Decision date	Feb 10, 2015
Days to decision	210 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...
