

K183352 Optimus Neuro SystemJan 2, 2019
30 days to decisionK183352 · Product code: **GWO** · Neurology
Source: <https://www.510kdatabase.net/k183352/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Cranioplasty, Preformed, Alterable (GWO)
Date received	Dec 3, 2018
Decision date	Jan 2, 2019
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Osteonic Co., Ltd.
Location	Seoul, KR
Contact	Seyoung Choi
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...

REGULATORY CONSULTANT

Consulting firm	Bt Solutions, Inc.
Contact	Jung Hyeon Park

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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Device record: <https://www.510kdatabase.net/k183352/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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