

K210360 Neuro Plating System, Neuro Plating System Plates(NST304M02A and 61 Models), Neuro Plating System-Packaging unit(NSP-001 and 10 models), Neuro Plating System-Sterile Kit(TCN-011 and 69 models), Neuro Plating System-Screws(N15A03 and 11 models)

Jan 27, 2022
353 days to decision

K210360 · Product code: **GWO** · Neurology
Source: <https://www.510kdatabase.net/k210360/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Cranioplasty, Preformed, Alterable (GWO)
Date received	Feb 8, 2021
Decision date	Jan 27, 2022
Days to decision	353 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Osteonic Co., Ltd.
Location	Seoul, KR
Contact	Na Young Kang
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	Wise Company, Inc.
Contact	Sanglok Lee

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/k210360/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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