

K190811 Optimus NEURO System - Sterile KitNov 27, 2019
243 days to decisionK190811 · Product code: **GWO** · Neurology
Source: <https://www.510kdatabase.net/k190811/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plate, Cranioplasty, Preformed, Alterable (GWO) |
| Date received | Mar 29, 2019 |
| Decision date | Nov 27, 2019 |
| Days to decision | 243 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Osteonic Co., Ltd. |
| Location | Seoul, KR |
| Contact | Choi Se Young |
| 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...