

K150918 PASS OCT Spinal SystemOct 16, 2015
193 days to decisionK150918 · Product code: **NKG** · Orthopedic
Source: <https://www.510kdatabase.net/k150918/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Posterior Cervical Screw System (NKG) |
| Date received | Apr 6, 2015 |
| Decision date | Oct 16, 2015 |
| Days to decision | 193 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Medicrea International SA |
| Location | Neyron, FR |
| Contact | Jean-Denys Marechal |
| 510(k) history | 25 submissions · 25 cleared · 2015-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150918/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026