

K201543 MAGEC® SystemJul 30, 2020
51 days to decisionK201543 · Product code: **PGN** · Orthopedic
Source: <https://www.510kdatabase.net/k201543/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Growing Rod System- Magnetic Actuation (PGN) |
| Date received | Jun 9, 2020 |
| Decision date | Jul 30, 2020 |
| Days to decision | 51 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Nuvasive Specialized Orthopedics, Inc. |
| Location | Alisa Viejo, CA, US |
| Contact | Ivanna Lopez |
| 510(k) history | 20 submissions · 20 cleared · 2016-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201543/> 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 14, 2026