

K190418 NuVasive® VersaTie® SystemMar 21, 2019
28 days to decisionK190418 · Product code: **OWI** · Orthopedic
Source: <https://www.510kdatabase.net/k190418/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Bone Fixation Cerclage, Sublaminar (OWI) |
| Date received | Feb 21, 2019 |
| Decision date | Mar 21, 2019 |
| Days to decision | 28 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Nu Vasive, Incorporated |
| Location | San Diego, CA, US |
| Contact | Joseph De La Rosa |
| 510(k) history | 112 submissions · 112 cleared · 2012-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190418/> 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 16, 2026