

**K193396 PERLA® TL posterior osteosynthesis system**Feb 5, 2020  
61 days to decisionK193396 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k193396/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Traditional                                   |
| Device classification | Thoracolumbosacral Pedicle Screw System (NKB) |
| Date received         | Dec 6, 2019                                   |
| Decision date         | Feb 5, 2020                                   |
| Days to decision      | 61 days                                       |
| Third-party review    | No  |
| Summary / Statement   | Summary                                       |

**APPLICANT**

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|----------------|---|
| Company        | <b>Spineart</b>                         |
| Location       | Geneva, CH                              |
| Contact        | Franck Pennesi                          |
| 510(k) history | 44 submissions · 44 cleared · 2008-2023 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193396/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 15, 2026