

K180433 ENNOVATE®Apr 26, 2018
65 days to decisionK180433 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k180433/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Thoracolumbosacral Pedicle Screw System (NKB) |
| Date received | Feb 20, 2018 |
| Decision date | Apr 26, 2018 |
| Days to decision | 65 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Aesculap Implant Systems, LLC |
| Location | Center Valley, PA, US |
| Contact | Melanie Burkert |
| 510(k) history | 22 submissions · 22 cleared · 2010-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180433/> 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