

K152920 Savannah-T® Pedicle Screw SystemJul 8, 2016
280 days to decisionK152920 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k152920/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Thoracolumbosacral Pedicle Screw System (NKB) |
| Date received | Oct 2, 2015 |
| Decision date | Jul 8, 2016 |
| Days to decision | 280 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Amendia, Inc. |
| Location | Apple Valley, MN, US |
| Contact | KRISTEN ALLEN |
| 510(k) history | 16 submissions · 16 cleared · 2009-2016 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152920/> 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