

K111957 POLARIS SPINAL SYSTEMAug 19, 2011
39 days to decisionK111957 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k111957/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Thoracolumbosacral Pedicle Screw System (NKB) |
| Date received | Jul 11, 2011 |
| Decision date | Aug 19, 2011 |
| Days to decision | 39 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Biomet Spine (Ebi, LLC) |
| Location | Parsippany, NJ, US |
| Contact | VIVIAN KELLY, RAC |
| 510(k) history | 1 submissions · 1 cleared · 2011-2011 |

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