

K083089 NEWPORT SPINAL SYSTEMJan 13, 2009
89 days to decisionK083089 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k083089/>**SUBMISSION DETAILS**

| | |
|-----------------------|-----------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Thoracolumbosacral Pedicle Screw System (NKB) |
| Date received | Oct 16, 2008 |
| Decision date | Jan 13, 2009 |
| Days to decision | 89 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Seaspine, Inc. |
| Location | Vista, CA, US |
| Contact | ETHEL BERNAL |
| 510(k) history | 27 submissions · 27 cleared · 2005-2023 |

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