

K053336 STAXX FX SYSTEMJul 3, 2006
214 days to decisionK053336 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k053336/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Cement, Bone, Vertebroplasty (NDN) |
| Date received | Dec 1, 2005 |
| Decision date | Jul 3, 2006 |
| Days to decision | 214 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Spine Wave, Inc. |
| Location | Shelton, CT, US |
| Contact | RONALD K SMITH |
| 510(k) history | 57 submissions · 57 cleared · 2004-2025 |

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