

K171570 Additional VIPER PRIME™ screws with fenestrationsAug 31, 2017
93 days to decisionK171570 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k171570/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Thoracolumbosacral Pedicle Screw System (NKB) |
| Date received | May 30, 2017 |
| Decision date | Aug 31, 2017 |
| Days to decision | 93 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Medos International SARL |
| Location | Raynham, MA, US |
| Contact | Karen Sylvia |
| 510(k) history | 96 submissions · 96 cleared · 2010-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171570/> 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 16, 2026