

K163181 TRANSLACE™ Spinal Tethering System

May 16, 2017
 183 days to decision

K163181 · Product code: **OWI** · Orthopedic
 Source: <https://www.510kdatabase.net/k163181/>

SUBMISSION DETAILS

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Bone Fixation Cerclage, Sublaminar (OWI) |
| Date received | Nov 14, 2016 |
| Decision date | May 16, 2017 |
| Days to decision | 183 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Medtronic Sofamor Danek USA, Inc. |
| Location | Memphis, TN, US |
| Contact | Becky Ronner |
| 510(k) history | 170 submissions · 159 cleared · 2000-2026 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k163181/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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