

**K943827 SPINE FIXATION**Feb 14, 1996  
558 days to decisionK943827 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k943827/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent - SN                     |
| Submission type       | Traditional                                       |
| Device classification | Orthosis, Spondylolisthesis Spinal Fixation (MNH) |
| Date received         | Aug 5, 1994                                       |
| Decision date         | Feb 14, 1996                                      |
| Days to decision      | 558 days  |
| Third-party review    | No  |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Danek Medical, Inc.</b>              |
| Location       | Mchenry, IL, US                         |
| Contact        | RICK TREHARNE                           |
| 510(k) history | 56 submissions · 47 cleared · 1981-2000 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943827/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 21, 2026