

**K103440 EVEREST SPINAL SYSTEM**Mar 17, 2011  
114 days to decisionK103440 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k103440/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Orthosis, Spinal Pedicle Fixation (MNI) |
| Date received         | Nov 23, 2010                            |
| Decision date         | Mar 17, 2011                            |
| Days to decision      | 114 days                                |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

---

|                |  |
|----------------|--|
| Company        | <b>K2m, Inc.</b>                         |
| Location       | Leesburg, VA, US                         |
| Contact        | NANCY GIEZEN                             |
| 510(k) history | 100 submissions · 97 cleared · 2007-2026 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103440/> 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 18, 2026