

**K984348 TIMX LOW BACK SYSTEM**Jan 20, 1999  
47 days to decisionK984348 · Product code: **MNI** · Orthopedic  
Source: <https://www.510kdatabase.net/k984348/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Dec 4, 1998
Decision date	Jan 20, 1999
Days to decision	47 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Depuy Motech Acromed</b>
Location	Cleveland, OH, US
Contact	PAM CORSILLO
510(k) history	4 submissions · 4 cleared · 1998-1999

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k984348/> 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