

**K041075 FASTIN RC ANCHOR**Nov 9, 2004  
197 days to decisionK041075 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k041075/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Apr 26, 2004
Decision date	Nov 9, 2004
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Depuy Mitek, A Johnson &amp; Johnson Company</b>
Location	Norwood, MA, US
Contact	KAREN SYLVIA
510(k) history	58 submissions · 58 cleared · 2004-2015

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k041075/> 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 14, 2026