

**K102443 INTRAFIX TIBIAL SHEATH**Oct 20, 2010  
55 days to decisionK102443 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k102443/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Aug 26, 2010
Decision date	Oct 20, 2010
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k102443/> 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