

**K013553 PRE-LOADED ULTRAFIX RC**Dec 19, 2001  
55 days to decisionK013553 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k013553/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Oct 25, 2001
Decision date	Dec 19, 2001
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Linvatec Corp.</b>
Location	Research Triangle Pa, NC, US
Contact	LAURA D SENEFF
510(k) history	93 submissions · 87 cleared · 1992-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013553/> 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