

**K012078 RADIOFIX**Sep 27, 2001  
87 days to decisionK012078 · Product code: **KTT** · Orthopedic  
Source: <https://www.510kdatabase.net/k012078/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Jul 2, 2001
Decision date	Sep 27, 2001
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fixano SA</b>
Location	La Jolla, CA, US
Contact	FRANK FERGUSON
510(k) history	5 submissions · 5 cleared · 2001-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012078/> 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 20, 2026