

**K012161 FLEX-NAILS**Aug 24, 2001  
44 days to decisionK012161 · Product code: **HTY** · Orthopedic  
Source: <https://www.510kdatabase.net/k012161/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Jul 11, 2001
Decision date	Aug 24, 2001
Days to decision	44 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/k012161/> 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