

**K122210 NEWFIX EXTERNAL FIXATION SYSTEM**Apr 19, 2013  
268 days to decisionK122210 · Product code: **KTT** · Orthopedic  
Source: <https://www.510kdatabase.net/k122210/>**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 25, 2012
Decision date	Apr 19, 2013
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tecnologia Y Diseno Industrial, S.A DE C.V</b>
Location	South Lyon, MI, US
Contact	ROBERT J BARD
510(k) history	2 submissions · 2 cleared · 2010-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122210/> 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 18, 2026