

**K073375 NEWDEAL TIBIAXYS SYSTEM**Feb 21, 2008  
80 days to decisionK073375 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k073375/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Dec 3, 2007
Decision date	Feb 21, 2008
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Newdeal Sas</b>
Location	Planisboro, NJ, US
Contact	JUDITH O'GRADY
510(k) history	10 submissions · 10 cleared · 2007-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k073375/> 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