

**K011262 MODIFICATION TO THE BOLD SCREW**Jun 15, 2001  
51 days to decisionK011262 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k011262/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Apr 25, 2001
Decision date	Jun 15, 2001
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>New Deal, S.A.</b>
Location	Potomac, MD, US
Contact	NORMAN F ESTRIN
510(k) history	28 submissions · 28 cleared · 1999-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011262/> 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 21, 2026