

**K991964 EIS THREADED SCREW FRACTURE FIXATION**Dec 20, 1999  
193 days to decisionK991964 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k991964/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jun 10, 1999
Decision date	Dec 20, 1999
Days to decision	193 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Groupe Lepine</b>
Location	Sarasota, FL, US
Contact	DOUGLAS W STUART
510(k) history	2 submissions · 2 cleared · 1999-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k991964/> 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