

**K161904 GEO Bone Screw System**Jan 18, 2017  
191 days to decisionK161904 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k161904/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jul 11, 2016
Decision date	Jan 18, 2017
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gramercy Extremity Orthopeidics, LLC</b>
Location	Richardson, TX, US
Contact	MICHAEL P. SIMPSON
510(k) history	1 submissions · 1 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161904/> 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 16, 2026