

**K140086 PERSONAL KINETIGRAPH (PKG) SYSTEM**Aug 22, 2014  
220 days to decisionK140086 · Product code: **GYD** · Neurology  
Source: <https://www.510kdatabase.net/k140086/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Tremor (GYD)
Date received	Jan 14, 2014
Decision date	Aug 22, 2014
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gkc Manufacturing Pty, Ltd.</b>
Location	Rockville, MD, US
Contact	MARIE SCHROEDER
510(k) history	3 submissions · 3 cleared · 2014-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140086/> 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 27, 2026