

**K851928 HEK GENCELLS**May 20, 1985  
18 days to decisionK851928 · Product code: **KIR** · Pathology  
Source: <https://www.510kdatabase.net/k851928/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cells, Animal And Human, Cultured (KIR)
Date received	May 2, 1985
Decision date	May 20, 1985
Days to decision	18 days
Third-party review	No

**APPLICANT**

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Company	<b>Genus Diagnostics</b>
Location	Woburn, MA, US
Contact	PETER J MIONE
510(k) history	9 submissions · 9 cleared · 1985-1986

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k851928/>; 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 14, 2026