

K852206 HEP-2 GENCELLSJun 4, 1985
14 days to decisionK852206 · Product code: **KIR** · Pathology
Source: <https://www.510kdatabase.net/k852206/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cells, Animal And Human, Cultured (KIR)
Date received	May 21, 1985
Decision date	Jun 4, 1985
Days to decision	14 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k852206/>; Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026