

K851561 WI-38 GENCELLSMay 10, 1985
24 days to decisionK851561 · Product code: **KIR** · Pathology
Source: <https://www.510kdatabase.net/k851561/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cells, Animal And Human, Cultured (KIR)
Date received	Apr 16, 1985
Decision date	May 10, 1985
Days to decision	24 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

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