

**K854974 HSV IDR**Mar 7, 1986  
85 days to decisionK854974 · Product code: **GQN** · Microbiology  
Source: <https://www.510kdatabase.net/k854974/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Control), Herpesvirus Homini 1,2 (GQN)
Date received	Dec 12, 1985
Decision date	Mar 7, 1986
Days to decision	85 days
Third-party review	No

**APPLICANT**

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Company	<b>Genus Diagnostics</b>
Location	Woburn, MA, US
Contact	MARK P BEAR
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/k854974/>; 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