

**K853307 DIRECT ELISA FOR HERPES SIMPLEX VIRUS**Dec 23, 1985  
138 days to decisionK853307 · Product code: **GQN** · Microbiology  
Source: <https://www.510kdatabase.net/k853307/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Control), Herpesvirus Hominis 1,2 (GQN)
Date received	Aug 7, 1985
Decision date	Dec 23, 1985
Days to decision	138 days
Third-party review	No

**APPLICANT**

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Company	<b>Fairleigh Dickinson Laboratories, Inc.</b>
Location	Allendale, NJ, US
Contact	TERRY L FOSTER
510(k) history	7 submissions · 7 cleared · 1985-1990

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k853307/>; 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 June 30, 2026