

**K875311 WELLCOZYME HSV WZO2**Aug 3, 1988  
218 days to decisionK875311 · Product code: **GQN** · Microbiology  
Source: <https://www.510kdatabase.net/k875311/>**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	Dec 29, 1987
Decision date	Aug 3, 1988
Days to decision	218 days
Third-party review	No

**APPLICANT**

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Company	<b>Wellcome Diagnostics</b>
Location	Walker, MI, US
Contact	MOODY, PHD
510(k) history	28 submissions · 28 cleared · 1983-1992

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k875311/>, 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 29, 2026