

**K905385 P.I.V. COMPLEMENT-FIXATION (C.F.) ANTIGEN**Mar 21, 1991  
111 days to decisionK905385 · Product code: **GQS** · Microbiology  
Source: <https://www.510kdatabase.net/k905385/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                                 |
| Submission type       | Traditional  |
| Device classification | Antigens, Cf (including Cf Control), Parainfluenza Virus 1-4 (GQS) |
| Date received         | Nov 30, 1990   |
| Decision date         | Mar 21, 1991   |
| Days to decision      | 111 days   |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Virion (U.S.), Inc.</b>            |
| Location       | Morristown, NJ, US                    |
| Contact        | HAUSLER, JR.                          |
| 510(k) history | 5 submissions · 5 cleared · 1987-1994 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k905385/>; 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