

**K864565 MONABRITE CYTOMEGALOVIRUS (CMV) IFA KIT**Feb 19, 1987  
92 days to decisionK864565 · Product code: **GQH** · Microbiology  
Source: <https://www.510kdatabase.net/k864565/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                        |
| Submission type       | Traditional   |
| Device classification | Antigen, Cf (including Cf Control), Cytomegalovirus (GQH) |
| Date received         | Nov 19, 1986  |
| Decision date         | Feb 19, 1987  |
| Days to decision      | 92 days   |
| Third-party review    | No  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Serono Diagnostics, Inc.</b>         |
| Location       | Walker, MI, US                          |
| Contact        | PHILIP M FANTASIA                       |
| 510(k) history | 25 submissions · 25 cleared · 1984-1996 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k864565/>; 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 28, 2026