

**K853540 FIAX TEST KIT FOR VARICELLA ANTIBODY  
SEROLOGY**Feb 4, 1986  
165 days to decisionK853540 · Product code: **GQX** · Microbiology  
Source: <https://www.510kdatabase.net/k853540/>**SUBMISSION DETAILS**

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|                       |                                       |
|-----------------------|---------------------------------------|
| Decision              | Substantially Equivalent (Cleared)    |
| Submission type       | Traditional                           |
| Device classification | Antiserum, Cf, Varicella-zoster (GQX) |
| Date received         | Aug 23, 1985                          |
| Decision date         | Feb 4, 1986                           |
| Days to decision      | 165 days                              |
| Third-party review    | No                                    |

**APPLICANT**

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| Company        | <b>Idt, A Division of Whittaker M.A. Bioproducts</b> |
| Location       | Mchenry, IL, US                                      |
| Contact        | LOUISE HARRIS  |
| 510(k) history | 5 submissions · 5 cleared · 1977-1986                |

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k853540/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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