

**K872958 IMAGEN INFLUENZA VIRUS A AND B TESTMI**Feb 24, 1988  
210 days to decisionK872958 · Product code: **GNX** · Microbiology  
Source: <https://www.510kdatabase.net/k872958/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                                 |
| Submission type       | Traditional  |
| Device classification | Antigens, Cf (including Cf Control), Influenza Virus A, B, C (GNX) |
| Date received         | Jul 29, 1987   |
| Decision date         | Feb 24, 1988   |
| Days to decision      | 210 days   |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Boots-Celltech Diagnostics, Inc.</b> |
| Location       | Walker, MI, US                          |
| Contact        | JOHN G SIMPSON                          |
| 510(k) history | 20 submissions · 20 cleared · 1984-1989 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k872958/>; 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