

**K885004 BACTIGEN(R) N. MENINGITIDIS**Feb 7, 1989  
68 days to decisionK885004 · Product code: **GTJ** · Microbiology  
Source: <https://www.510kdatabase.net/k885004/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)          |
| Submission type       | Traditional                                 |
| Device classification | Antisera, All Groups, N. Meningitidis (GTJ) |
| Date received         | Dec 1, 1988                                 |
| Decision date         | Feb 7, 1989                                 |
| Days to decision      | 68 days                                     |
| Third-party review    | No  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Armkel, LLC</b>                      |
| Location       | Mchenry, IL, US                         |
| Contact        | ANN MACLEARIE                           |
| 510(k) history | 68 submissions · 68 cleared · 1979-2004 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k885004/>; 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