

**K884966 BACTIGEN(R) S. PNEUMONIAE**Feb 7, 1989  
69 days to decisionK884966 · Product code: **GWC** · Microbiology  
Source: <https://www.510kdatabase.net/k884966/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Traditional   |
| Device classification | Antisera, All Types, Streptococcus Pneumoniae (GWC) |
| Date received         | Nov 30, 1988  |
| Decision date         | Feb 7, 1989   |
| Days to decision      | 69 days   |
| Third-party review    | No  |

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k884966/>; 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