

**K082661 BIOSTREP A, BIOSIGN STREP A, STATUSFIRST STREP A**Oct 6, 2008  
24 days to decisionK082661 · Product code: **GTY** · Microbiology  
Source: <https://www.510kdatabase.net/k082661/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Special  |
| Device classification | Antigens, All Groups, Streptococcus Spp. (GTY) |
| Date received         | Sep 12, 2008                                   |
| Decision date         | Oct 6, 2008                                    |
| Days to decision      | 24 days  |
| Third-party review    | No   |
| Summary / Statement   | Statement                                      |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Princeton BioMeditech Corp.</b>      |
| Location       | Monmouth Junction, NJ, US               |
| Contact        | KYUNG-AH KIM                            |
| 510(k) history | 72 submissions · 72 cleared · 1994-2025 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082661/> Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026