

K182157 BioSign Flu A+BSep 18, 2018
40 days to decisionK182157 · Product code: **PSZ** · Microbiology
Source: <https://www.510kdatabase.net/k182157/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Devices Detecting Influenza A, B, And C Virus Antigens (PSZ) |
| Date received | Aug 9, 2018 |
| Decision date | Sep 18, 2018 |
| Days to decision | 40 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Princeton BioMeditech Corp. |
| Location | Monmouth Junction, NJ, US |
| Contact | Kyung-ah Kim |
| 510(k) history | 72 submissions · 72 cleared · 1994-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182157/> 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 14, 2026