

**K111517 PHARMAJET STRATIS 0.5 ML NEEDLE-FREE
INJECTION SYSTEM MODEL 501-01, STRATIS INJECTOR
CATALOG 501-10, STRATIS RESET STATI**Jul 27, 2011
55 days to decisionK111517 · Product code: **KZE** · General Hospital
Source: <https://www.510kdatabase.net/k111517/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Injector, Fluid, Non-electrically Powered (KZE) |
| Date received | Jun 2, 2011 |
| Decision date | Jul 27, 2011 |
| Days to decision | 55 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Pharmajet, Inc. |
| Location | Golden, CO, US |
| Contact | MICHAEL J RYAN |
| 510(k) history | 3 submissions · 3 cleared · 2009-2011 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111517/>; 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 June 18, 2026