

K153706 Insulin Pen NeedleAug 29, 2016
250 days to decisionK153706 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k153706/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Needle, Hypodermic, Single Lumen (FMI) |
| Date received | Dec 23, 2015 |
| Decision date | Aug 29, 2016 |
| Days to decision | 250 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | SteriLance Medical (Suzhou), Inc. |
| Location | Suzhou, CN |
| Contact | Juanjuan Sun |
| 510(k) history | 8 submissions · 8 cleared · 2016-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153706/> 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