

K190427 ImmuciseJul 18, 2019
146 days to decisionK190427 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k190427/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Syringe, Piston (FMF) |
| Date received | Feb 22, 2019 |
| Decision date | Jul 18, 2019 |
| Days to decision | 146 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Terumo Corporation |
| Location | Shibuya-Ku, Tokyo, JP |
| Contact | Rudima L Jackson |
| 510(k) history | 13 submissions · 13 cleared · 2012-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190427/> 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 24, 2026