

K110850 K-PACK II NEEDLE- 27G & 30G THIN WALLJun 9, 2011
73 days to decisionK110850 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k110850/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Needle, Hypodermic, Single Lumen (FMI) |
| Date received | Mar 28, 2011 |
| Decision date | Jun 9, 2011 |
| Days to decision | 73 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Terumo Europe N.V. |
| Location | Leuven, BE |
| Contact | M.J. AERTS |
| 510(k) history | 28 submissions · 28 cleared · 1999-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110850/> 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 19, 2026