FDA 510(k) Premarket Notification

# K082820 K-PACK II NEEDLE - 29G THIN WALL

**CLEARED**

Oct 23, 2008
28 days to decision

K082820 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k082820/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Needle, Hypodermic, Single Lumen (FMI) |
| Date received | Sep 25, 2008 |
| Decision date | Oct 23, 2008 |
| Days to decision | 28 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 |