

K133867 SURFLO WINGED INFUSION SET WITH NEEDLE PROTECTION (SURSHIELD)Feb 5, 2014
47 days to decisionK133867 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k133867/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received | Dec 20, 2013 |
| Decision date | Feb 5, 2014 |
| Days to decision | 47 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/k133867/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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