

K122544 TERUMO SURFLASH SAFETY I.V. CATHETERSep 5, 2012
15 days to decisionK122544 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k122544/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ) |
| Date received | Aug 21, 2012 |
| Decision date | Sep 5, 2012 |
| Days to decision | 15 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122544/> 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