

K943047 IV START KITSSep 14, 1994
79 days to decisionK943047 · Product code: **KMK** · General Hospital
Source: <https://www.510kdatabase.net/k943047/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, Intravascular Catheter Securement (KMK) |
| Date received | Jun 27, 1994 |
| Decision date | Sep 14, 1994 |
| Days to decision | 79 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Sterile Concepts, Inc. |
| Location | Richmond, VA, US |
| Contact | KAY ANDREWS |
| 510(k) history | 10 submissions · 7 cleared · 1992-1995 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k943047/> 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 29, 2026