

K030723 IVS INTRODUCER SET, MODEL 1003Apr 3, 2003
27 days to decisionK030723 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k030723/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Introducer, Catheter (DYB) |
| Date received | Mar 7, 2003 |
| Decision date | Apr 3, 2003 |
| Days to decision | 27 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Integrated Vascular Systems, Inc. |
| Location | Sunnyvale, CA, US |
| Contact | SUSAN TURNER |
| 510(k) history | 3 submissions · 3 cleared · 2002-2003 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k030723/> 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 July 3, 2026