

K935077 CATH-SEALJun 7, 1994
228 days to decisionK935077 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k935077/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Introducer, Catheter (DYB) |
| Date received | Oct 22, 1993 |
| Decision date | Jun 7, 1994 |
| Days to decision | 228 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Universal Medical Instrument Corp. |
| Location | Mchenry, IL, US |
| Contact | DERON A JORDAN |
| 510(k) history | 21 submissions · 21 cleared · 1977-1996 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k935077/> 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 30, 2026