

**K894445 MODIFIED SOFTOUCH INTRODUCER W/HEMO VALVE
& SIDE**Oct 2, 1989
77 days to decisionK894445 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k894445/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Introducer, Catheter (DYB) |
| Date received | Jul 17, 1989 |
| Decision date | Oct 2, 1989 |
| Days to decision | 77 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Mallinckroot, Inc. |
| Location | Argyle, NY, US |
| Contact | DAVID E BROWN |
| 510(k) history | 7 submissions · 7 cleared · 1988-1999 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k894445/>; 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 27, 2026