

K894446 ANGEION HEMOSTASIS VALVE INTRODUCERNov 30, 1989
136 days to decisionK894446 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k894446/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Introducer, Catheter (DYB) |
| Date received | Jul 17, 1989 |
| Decision date | Nov 30, 1989 |
| Days to decision | 136 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Angeion Corp. |
| Location | Plymouth, MN, US |
| Contact | GREGORY G BRUCKER |
| 510(k) history | 7 submissions · 7 cleared · 1987-1993 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k894446/>; 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 2, 2026