

**K923367 COSGROVE EDWARDS ANNULOPLASTY SYSTEM,
MODEL 4600**Jan 6, 1993
181 days to decisionK923367 · Product code: **KRH** · Cardiovascular
Source: <https://www.510kdatabase.net/k923367/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------|
| Decision | Substantially Equivalent - SP |
| Submission type | Traditional |
| Device classification | Ring, Annuloplasty (KRH) |
| Date received | Jul 9, 1992 |
| Decision date | Jan 6, 1993 |
| Days to decision | 181 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Baxter Healthcare Corp |
| Location | Mchenry, IL, US |
| Contact | Roberta Hines |
| 510(k) history | 505 submissions · 496 cleared · 1977-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k923367/>; 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 17, 2026