FDA 510(k) Premarket Notification

# K882508 9.5 FRENCH PERCUTANEOUS DOUBLE LUMEN BALLOON

**CLEARED**

Mar 20, 1989
276 days to decision

K882508 · Product code: **DSP** · Cardiovascular
Source: https://www.510kdatabase.net/k882508/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Balloon, Intra-aortic And Control (DSP) |
| Date received | Jun 17, 1988 |
| Decision date | Mar 20, 1989 |
| Days to decision | 276 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Kontron Instruments, Inc.** |
| Location | Mchenry, IL, US |
| Contact | DAVID CROMWICK |
| 510(k) history | 57 submissions · 57 cleared · 1981-1993 |

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k882508/ 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 21, 2026