

K915627 PACEVIEWMar 27, 1992
109 days to decisionK915627 · Product code: **KRB** · Cardiovascular
Source: <https://www.510kdatabase.net/k915627/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Probe, Thermodilution (KRB) |
| Date received | Dec 9, 1991 |
| Decision date | Mar 27, 1992 |
| Days to decision | 109 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Micromedical Industries, Ltd. |
| Location | Northbrook, IL, US |
| Contact | EDWARD HAWFIELD |
| 510(k) history | 6 submissions · 6 cleared · 1992-2002 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k915627/> 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 3, 2026