

K791026 4F STERILE BALLOON-LESS, CATHETER 913-28Jun 22, 1979
18 days to decisionK791026 · Product code: **KRB** · CardiovascularSource: <https://www.510kdatabase.net/k791026/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Probe, Thermodilution (KRB) |
| Date received | Jun 4, 1979 |
| Decision date | Jun 22, 1979 |
| Days to decision | 18 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Waters Assoc., Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 16 submissions · 16 cleared · 1976-1981 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k791026/> 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 22, 2026