

K935655 ABL5 BLOOD GAS SYSTEMMay 27, 1994
184 days to decisionK935655 · Product code: **CHL** · Chemistry
Source: <https://www.510kdatabase.net/k935655/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrode Measurement, Blood-gases (pco2, Po2) And Blood Ph (CHL) |
| Date received | Nov 24, 1993 |
| Decision date | May 27, 1994 |
| Days to decision | 184 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Radiometer America, Inc. |
| Location | Mchenry, IL, US |
| Contact | DONALD L BAKER |
| 510(k) history | 50 submissions · 50 cleared · 1983-2016 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k935655/> 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 27, 2026