

**K895582 QCLYTE PROTEIN-BASED ISE CONTROL**Oct 4, 1989  
19 days to decisionK895582 · Product code: **JJR** · Chemistry  
Source: <https://www.510kdatabase.net/k895582/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrolyte Controls (assayed And Unassayed) (JJR)
Date received	Sep 15, 1989
Decision date	Oct 4, 1989
Days to decision	19 days
Third-party review	No

**APPLICANT**

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Company	<b>Baxter Healthcare Corp</b>
Location	Mchenry, IL, US
Contact	KRISTA U SMALLEY
510(k) history	505 submissions · 496 cleared · 1977-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k895582/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 17, 2026