

**K993631 QUALITROL TUMOR MARKER CONTROL, LEVELS 1  
AND 2**Dec 9, 1999  
43 days to decisionK993631 · Product code: **JJY** · Immunology  
Source: <https://www.510kdatabase.net/k993631/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Oct 27, 1999
Decision date	Dec 9, 1999
Days to decision	43 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Seracare Technology</b>
Location	Austin, TX, US
Contact	RUSTY SEWELL
510(k) history	5 submissions · 5 cleared · 1999-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k993631/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026