

**K860923 EZ DETECT, 5 MINUTE STREP-A COLOR TEST**May 16, 1986  
66 days to decisionK860923 · Product code: **GTZ** · Microbiology  
Source: <https://www.510kdatabase.net/k860923/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Mar 11, 1986
Decision date	May 16, 1986
Days to decision	66 days
Third-party review	No

**APPLICANT**

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Company	<b>Self Care Systems, Inc.</b>
Location	Newport Beach, CA, US
Contact	CHANDRAVADAN PATEL
510(k) history	3 submissions · 3 cleared · 1986-1986

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k860923/>; 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 June 29, 2026