

**K864170 LEECO VIS-CUBE STREP A (EIA)**Feb 3, 1987  
102 days to decisionK864170 · Product code: **GTZ** · Microbiology  
Source: <https://www.510kdatabase.net/k864170/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Oct 24, 1986
Decision date	Feb 3, 1987
Days to decision	102 days
Third-party review	No

**APPLICANT**

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Company	<b>Leeco Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	LEE, PH.D.
510(k) history	49 submissions · 49 cleared · 1979-1989

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k864170/>, 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 30, 2026