

**K831991 DIRECTIGEN GROUP B STREP TEST KIT-SERUM**Sep 26, 1983  
97 days to decisionK831991 · Product code: **GTZ** · Microbiology  
Source: <https://www.510kdatabase.net/k831991/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Jun 21, 1983
Decision date	Sep 26, 1983
Days to decision	97 days
Third-party review	No

**APPLICANT**

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Company	<b>Bd Becton Dickinson Vacutainer Systems Preanalytic</b>
Location	Washington, DC, US
510(k) history	632 submissions · 625 cleared · 1976-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k831991/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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