

**K983386 BIOSTREP A-DIRECT STREP A ANTIGEN TEST**Nov 25, 1998  
60 days to decisionK983386 · Product code: **GTY** · Microbiology  
Source: <https://www.510kdatabase.net/k983386/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Sep 26, 1998
Decision date	Nov 25, 1998
Days to decision	60 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Princeton BioMeditech Corp.</b>
Location	Monmouth Junction, NJ, US
Contact	JEMO KANG
510(k) history	72 submissions · 72 cleared · 1994-2025

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