

K971349 BIOSIGN STREP A - DIRECT STREP A ANTIGEN TESTJul 7, 1997
88 days to decisionK971349 · Product code: **GTY** · Microbiology
Source: <https://www.510kdatabase.net/k971349/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Apr 10, 1997
Decision date	Jul 7, 1997
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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