

K862133 HYGEIA RAPID STREP A TESTJun 25, 1986
21 days to decisionK862133 · Product code: **GTY** · Microbiology
Source: <https://www.510kdatabase.net/k862133/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Jun 4, 1986
Decision date	Jun 25, 1986
Days to decision	21 days
Third-party review	No

APPLICANT

Company	Hygeia Sciences
Location	Newton, MA, US
Contact	BERKE, PH.D.
510(k) history	4 submissions · 4 cleared · 1986-1988

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k862133/>; Data sourced from FDA 510(k) public records (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. - Generated June 30, 2026