

K091489 CLEARVIEW ADVANCED STREP A , MODEL 737-430Sep 4, 2009
107 days to decisionK091489 · Product code: **GTY** · Microbiology
Source: <https://www.510kdatabase.net/k091489/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	May 20, 2009
Decision date	Sep 4, 2009
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Binax, Inc.
Location	S. Portland, ME, US
Contact	ERIN E KENALEY
510(k) history	30 submissions · 30 cleared · 1986-2010

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