

K844399 RESPIRALEX LATEX AGGLUTINATION TESTJan 8, 1985
56 days to decisionK844399 · Product code: **GTZ** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Nov 13, 1984
Decision date	Jan 8, 1985
Days to decision	56 days
Third-party review	No

APPLICANT

Company	Orion Diagnostica, Inc.
Location	Mchenry, IL, US
Contact	CHERYL WEST
510(k) history	28 submissions · 28 cleared · 1980-1994

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