

K862475 RESPIRASTICK ENZYME IMMUNOASSAY TESTSep 16, 1986
78 days to decisionK862475 · Product code: **GTY** · Microbiology
Source: <https://www.510kdatabase.net/k862475/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Jun 30, 1986
Decision date	Sep 16, 1986
Days to decision	78 days
Third-party review	No

APPLICANT

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

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