

**K051638 INVERNESS MEDICAL TESTPACK + PLUS STREP A
WITH OBC**Dec 6, 2005
169 days to decisionK051638 · Product code: **GTY** · Microbiology
Source: <https://www.510kdatabase.net/k051638/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Jun 20, 2005
Decision date	Dec 6, 2005
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Unipath , Ltd.
Location	Bedford Mk41 Oqq, GB
Contact	Louise Roberts
510(k) history	73 submissions · 73 cleared · 1986-2006

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