

K992658 OSOM ULTRA STREP A TEST, MODEL 147Jan 18, 2000
162 days to decisionK992658 · Product code: **GTY** · Microbiology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Aug 9, 1999
Decision date	Jan 18, 2000
Days to decision	162 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Wyntek Diagnostics, Inc.
Location	San Diego, CA, US
Contact	SHU-CHING CHENG
510(k) history	12 submissions · 12 cleared · 1995-2000

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