

K133343 WONDFO RAPID STREP A TESTJan 31, 2014
93 days to decisionK133343 · Product code: **GTY** · Microbiology
Source: <https://www.510kdatabase.net/k133343/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Oct 30, 2013
Decision date	Jan 31, 2014
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Guangzhou Wondfo Biotech Co., Ltd.
Location	Yardley, PA, US
Contact	Joe Shia
510(k) history	43 submissions · 43 cleared · 2005-2026

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