

K895461 WELLCOLEX COLOUR SHIGELLA TEST ZC51Jan 11, 1990
127 days to decisionK895461 · Product code: **GNB** · Microbiology
Source: <https://www.510kdatabase.net/k895461/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Types, Shigella Spp. (GNB)
Date received	Sep 6, 1989
Decision date	Jan 11, 1990
Days to decision	127 days
Third-party review	No

APPLICANT

Company	Wellcome Diagnostics
Location	Walker, MI, US
Contact	J ROSENBERG
510(k) history	28 submissions · 28 cleared · 1983-1992

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