

K860768 DIRECTIGEN COMBO MENINGITIS TESTMay 13, 1986
71 days to decisionK860768 · Product code: **GTZ** · Microbiology
Source: <https://www.510kdatabase.net/k860768/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Mar 3, 1986
Decision date	May 13, 1986
Days to decision	71 days
Third-party review	No

APPLICANT

Company	Bd Becton Dickinson Vacutainer Systems Preanalytic
Location	Washington, DC, US
Contact	R. J ARNSBERGER
510(k) history	632 submissions · 625 cleared · 1976-2001

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