FDA 510(k) Premarket Notification

K843713 DIRECTIGEN GROUP A STREP TEST KIT

CLEARED

Jan 4, 1985
105 days to decision

K843713 · Product code: **GTZ** · Microbiology
Source: https://www.510kdatabase.net/k843713/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Groups, Streptococcus Spp. (GTZ)
Date received	Sep 21, 1984
Decision date	Jan 4, 1985
Days to decision	105 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k843713/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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