

K812808 BBL DIRECTIGEN TEST KITDec 30, 1981
85 days to decisionK812808 · Product code: **GTY** · Microbiology
Source: <https://www.510kdatabase.net/k812808/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Groups, Streptococcus Spp. (GTY)
Date received	Oct 6, 1981
Decision date	Dec 30, 1981
Days to decision	85 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k812808/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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