FDA 510(k) Premarket Notification

K832228 RUBASCAN LATEX CARD TEST

CLEARED

Sep 29, 1983
80 days to decision

K832228 · Product code: **GOK** · Microbiology
Source: https://www.510kdatabase.net/k832228/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, Hai (including Hai Control), Rubella (GOK)
Date received	Jul 11, 1983
Decision date	Sep 29, 1983
Days to decision	80 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k832228/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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