FDA 510(k) Premarket Notification

K802339 EIA RUBELLA-G

CLEARED

Dec 18, 1980
83 days to decision

K802339 · Product code: **GOL** · Microbiology
Source: https://www.510kdatabase.net/k802339/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Ha (including Ha Control), Rubella (GOL)
Date received	Sep 26, 1980
Decision date	Dec 18, 1980
Days to decision	83 days
Third-party review	No

APPLICANT

Company	**Beckman Instruments, Inc.**
Location	Mchenry, IL, US
Website	https://www.beckman.com
510(k) history	281 submissions · 281 cleared · 1976-1998

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k802339/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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