FDA 510(k) Premarket Notification

K780063 RUBENOSTICON

CLEARED

Jan 20, 1978
8 days to decision

K780063 · Product code: **GOK** · Microbiology
Source: https://www.510kdatabase.net/k780063/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, Hai (including Hai Control), Rubella (GOK)
Date received	Jan 12, 1978
Decision date	Jan 20, 1978
Days to decision	8 days
Third-party review	No

APPLICANT

Company	**Organon, Inc.**
Location	Mchenry, IL, US
510(k) history	41 submissions · 41 cleared · 1977-1995