FDA 510(k) Premarket Notification

K781638 RUBINDEX*DIRECT SYSTEM

CLEARED

Dec 20, 1978
90 days to decision

K781638 · Product code: **GOK** · Immunology
Source: https://www.510kdatabase.net/k781638/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, Hai (including Hai Control), Rubella (GOK)
Date received	Sep 21, 1978
Decision date	Dec 20, 1978
Days to decision	90 days
Third-party review	No

APPLICANT

Company	**Ortho Diagnostics, Inc.**
Location	Mchenry, IL, US
510(k) history	24 submissions · 24 cleared · 1977-1980