

K781638 RUBINDEX*DIRECT SYSTEMDec 20, 1978
90 days to decisionK781638 · 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k781638/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026