FDA 510(k) Premarket Notification

K791791 ORTHO ANTIBODY ENHANCEMENT SOLUTION

CLEARED

Oct 11, 1979
30 days to decision

K791791 · Product code: **KSG** · Hematology
Source: https://www.510kdatabase.net/k791791/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Potentiating For In Vitro Diagnostic Use (KSG)
Date received	Sep 11, 1979
Decision date	Oct 11, 1979
Days to decision	30 days
Third-party review	No

APPLICANT

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