FDA 510(k) Premarket Notification

K771488 P1 BLOOD GROUP SUBSTANCE

CLEARED

Nov 8, 1977
95 days to decision

K771488 · Product code: **KSX** · Hematology
Source: https://www.510kdatabase.net/k771488/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Substance, Blood Grouping Of Non-human Origin For In Vitro Diagnostic Use (KSX)
Date received	Aug 5, 1977
Decision date	Nov 8, 1977
Days to decision	95 days
Third-party review	No

APPLICANT

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