

**K771488 P1 BLOOD GROUP SUBSTANCE**Nov 8, 1977  
95 days to decisionK771488 · 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	<b>Ortho Diagnostics, Inc.</b>
Location	Mchenry, IL, US
510(k) history	24 submissions · 24 cleared · 1977-1980

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k771488/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026