

**K802534 GAMMA PI BLOOD GROUP SUBSTANCE**Nov 12, 1980  
28 days to decisionK802534 · Product code: **KSX** · Hematology  
Source: <https://www.510kdatabase.net/k802534/>**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	Oct 15, 1980
Decision date	Nov 12, 1980
Days to decision	28 days
Third-party review	No

**APPLICANT**

---

Company	<b>Gamma Biologicals, Inc.</b>
Location	Mchenry, IL, US
510(k) history	21 submissions · 21 cleared · 1976-1986

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k802534/>; 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