

K820647 GAMMA FETAL BLEED SCREENING TESTMay 12, 1982
64 days to decisionK820647 · Product code: **LIM** · Hematology
Source: <https://www.510kdatabase.net/k820647/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Screening, For D Positive Fetal Rbc's (LIM)
Date received	Mar 9, 1982
Decision date	May 12, 1982
Days to decision	64 days
Third-party review	No

APPLICANT

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

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