FDA 510(k) Premarket Notification

K820642 SICKLE-CHECK

CLEARED

Apr 14, 1982
37 days to decision

K820642 · Product code: **GHM** · Hematology
Source: https://www.510kdatabase.net/k820642/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Sickle Cell (GHM)
Date received	Mar 8, 1982
Decision date	Apr 14, 1982
Days to decision	37 days
Third-party review	No

APPLICANT

Company	**Panmed, Inc.**
Location	Mchenry, IL, US
510(k) history	16 submissions · 16 cleared · 1978-1986