FDA 510(k) Premarket Notification

K840011 RESOLVE-HB

CLEARED

Feb 4, 1984
31 days to decision

K840011 · Product code: **GKA** · Hematology
Source: https://www.510kdatabase.net/k840011/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abnormal Hemoglobin Quantitation (GKA)
Date received	Jan 4, 1984
Decision date	Feb 4, 1984
Days to decision	31 days
Third-party review	No

APPLICANT

Company	**Isolab, Inc.**
Location	Mchenry, IL, US
510(k) history	44 submissions · 44 cleared · 1977-1996