FDA 510(k) Premarket Notification

K880653 HBF DILUENT

CLEARED

Apr 21, 1988
64 days to decision

K880653 · Product code: **KQI** · Hematology
Source: https://www.510kdatabase.net/k880653/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Fetal Hemoglobin (KQI)
Date received	Feb 17, 1988
Decision date	Apr 21, 1988
Days to decision	64 days
Third-party review	No

APPLICANT

Company	**Helena Laboratories**
Location	Mchenry, IL, US
Contact	PAT FRANKS
510(k) history	280 submissions · 280 cleared · 1978-2013