FDA 510(k) Premarket Notification

K003359 COLOSCREEN-ES

CLEARED

Nov 27, 2000
31 days to decision

K003359 · Product code: **KHE** · Hematology
Source: https://www.510kdatabase.net/k003359/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Oct 27, 2000
Decision date	Nov 27, 2000
Days to decision	31 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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