FDA 510(k) Premarket Notification

K100103 SPECIALTY ASSAYED CONTROL-2

CLEARED

Dec 15, 2010
336 days to decision

K100103 · Product code: **GGC** · Hematology
Source: https://www.510kdatabase.net/k100103/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Plasma, Abnormal (GGC)
Date received	Jan 13, 2010
Decision date	Dec 15, 2010
Days to decision	336 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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