FDA 510(k) Premarket Notification

K112755 ABACUS 5

CLEARED

Mar 27, 2012
188 days to decision

K112755 · Product code: **GKZ** · Hematology
Source: https://www.510kdatabase.net/k112755/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Sep 21, 2011
Decision date	Mar 27, 2012
Days to decision	188 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Diatron U.S., Inc.**
Location	Lenexa, KS, US
Contact	MICHAEL SWITZER
510(k) history	3 submissions · 3 cleared · 2012-2016