FDA 510(k) Premarket Notification

K062306 PLASMACON N, PLASMACON L-1, PLASMACON L-2

CLEARED

Mar 16, 2007
220 days to decision

K062306 · Product code: **GGC** · Hematology
Source: https://www.510kdatabase.net/k062306/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Plasma, Abnormal (GGC)
Date received	Aug 8, 2006
Decision date	Mar 16, 2007
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**R2 Diagnostics, Inc.**
Location	South Bend, IN, US
Contact	MARC GOLDFORD
510(k) history	10 submissions · 10 cleared · 2004-2011