

K151133 PENTRA XLRDec 9, 2015
225 days to decisionK151133 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k151133/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Apr 28, 2015
Decision date	Dec 9, 2015
Days to decision	225 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	HORIBA ABX SAS
Location	Montpellier Cedex 4, FR
Contact	Caroline Ferrer
510(k) history	17 submissions · 17 cleared · 2009-2024

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