FDA 510(k) Premarket Notification

K172333 Sysmex CS-5100

CLEARED

Oct 31, 2017
90 days to decision

K172333 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k172333/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Aug 2, 2017
Decision date	Oct 31, 2017
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Healthcare Diagnostics Products GmbH**
Location	Marburg, DE
Contact	Donna Noeh
510(k) history	19 submissions · 18 cleared · 2016-2024