FDA 510(k) Premarket Notification

CLEARED

K173202 CP3000 Coagulation analyzer, Coagpia AT Reagent, Coagpia Calibrator, Coagpia Control Set

May 9, 2018
219 days to decision

K173202 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k173202/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Oct 2, 2017
Decision date	May 9, 2018
Days to decision	219 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sekisui Medical Co., Ltd.**
Location	Chuo-Ku, JP
Contact	Kazunori Saito
510(k) history	1 submissions · 1 cleared · 2018-2018