FDA 510(k) Premarket Notification

K992851 ACT TEST CATRIDGES FOR COAGUCHEK PRO SYSTEM, ACT CONTROLS FOR COAGUCHEK PRO SYSTEM

CLEARED

Jan 14, 2000
143 days to decision

K992851 · Product code: **JBP** · Hematology
Source: https://www.510kdatabase.net/k992851/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Activated Whole Blood Clotting Time (JBP)
Date received	Aug 24, 1999
Decision date	Jan 14, 2000
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Roche Diagnostics Corp.**
Location	Indianapolis, IN, US
Contact	LUANN OCHS
510(k) history	264 submissions · 263 cleared · 1999-2013