FDA 510(k) Premarket Notification

CLEARED

K002080 BEHRING COAGULATION SYSTEM, MODEL BCS

Nov 16, 2000
129 days to decision

K002080 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k002080/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Jul 10, 2000
Decision date	Nov 16, 2000
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dade Behring, Inc.**
Location	Newark,, DE, US
Contact	RADAMES RIESGO
510(k) history	343 submissions · 343 cleared · 1978-2010