K170864 VALIDATE D-Dimer Calibration Verification / Linearity Test Kit

CLEARED

Jun 21, 2017
90 days to decision

K170864 · Product code: **GGN** · Hematology
Source: https://www.510kdatabase.net/k170864/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Mar 23, 2017
Decision date	Jun 21, 2017
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Maine Standards Company, LLC**
Location	Windham, ME, US
Contact	James Champlin
510(k) history	7 submissions · 7 cleared · 2011-2017