FDA 510(k) Premarket Notification

K062203 TINA-QUANT D-DIMER TEST SYSTEM

CLEARED

Mar 14, 2007
225 days to decision

K062203 · Product code: **GHH** · Hematology
Source: https://www.510kdatabase.net/k062203/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrin Split Products (GHH)
Date received	Aug 1, 2006
Decision date	Mar 14, 2007
Days to decision	225 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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