FDA 510(k) Premarket Notification

K011143 TINA-QUANT D-DIMER TEST SYSTEM

CLEARED

May 29, 2001
46 days to decision

K011143 · Product code: **GHH** · Hematology
Source: https://www.510kdatabase.net/k011143/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fibrin Split Products (GHH)
Date received	Apr 13, 2001
Decision date	May 29, 2001
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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