FDA 510(k) Premarket Notification

K823520 FIBROSYSTEM

CLEARED

Dec 28, 1982
29 days to decision

K823520 · Product code: **GKQ** · Hematology
Source: https://www.510kdatabase.net/k823520/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Thromboplastin Generation (GKQ)
Date received	Nov 29, 1982
Decision date	Dec 28, 1982
Days to decision	29 days
Third-party review	No

APPLICANT

Company	**Bd Becton Dickinson Vacutainer Systems Preanalytic**
Location	Washington, DC, US
510(k) history	632 submissions · 625 cleared · 1976-2001