FDA 510(k) Premarket Notification

K884485 KD ACTIVATED PARTIAL THROMBOPLASTIN TIME REAGENT

CLEARED

Dec 28, 1988
64 days to decision

K884485 · Product code: **GFO** · Hematology
Source: https://www.510kdatabase.net/k884485/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Activated Partial Thromboplastin (GFO)
Date received	Oct 25, 1988
Decision date	Dec 28, 1988
Days to decision	64 days
Third-party review	No

APPLICANT

Company	**King Diagnostics, Inc.**
Location	Walker, MI, US
Contact	FRANCES LOH
510(k) history	41 submissions · 41 cleared · 1981-1993