FDA 510(k) Premarket Notification

K890619 EDL ACTIVATED PARTIAL THROMBOPLASTIN TIME REAGENT

CLEARED

Mar 15, 1989
36 days to decision

K890619 · Product code: **GFO** · Hematology
Source: https://www.510kdatabase.net/k890619/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Activated Partial Thromboplastin (GFO)
Date received	Feb 7, 1989
Decision date	Mar 15, 1989
Days to decision	36 days
Third-party review	No

APPLICANT

Company	**Elite Diagnostic , Ltd.**
Location	Indianapolis, IN, US
Contact	ROY SPECK
510(k) history	5 submissions · 5 cleared · 1989-1989