FDA 510(k) Premarket Notification

CLEARED

K860719 BIOTRACK PROTIME CONTROLS (BIOTRACK PROTIME TEST)

May 23, 1986
86 days to decision

K860719 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k860719/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Feb 26, 1986
Decision date	May 23, 1986
Days to decision	86 days
Third-party review	No

APPLICANT

Company	**Biotrack, Inc.**
Location	Sunnyvale, CA, US
Contact	JIM ALLEN
510(k) history	16 submissions · 16 cleared · 1986-1993