FDA 510(k) Premarket Notification

K802141 CH-60 PLUS WHOLE BLOOD PLATELET CONTROL

CLEARED

Oct 10, 1980
35 days to decision

K802141 · Product code: **JPK** · Hematology
Source: https://www.510kdatabase.net/k802141/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixture, Hematology Quality Control (JPK)
Date received	Sep 5, 1980
Decision date	Oct 10, 1980
Days to decision	35 days
Third-party review	No

APPLICANT

Company	**American Dade**
Location	Mchenry, IL, US
510(k) history	149 submissions · 149 cleared · 1980-1987