FDA 510(k) Premarket Notification

K840948 CLEAR POROUS PLASTIC-HYPOALLERGENIC

CLEARED

Aug 14, 1984
39 days to decision

K840948 · Product code: **GKX** · Hematology
Source: https://www.510kdatabase.net/k840948/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Automated Platelet Counting (GKX)
Date received	Jul 6, 1984
Decision date	Aug 14, 1984
Days to decision	39 days
Third-party review	No

APPLICANT

Company	**Gainor Medical**
Location	US
510(k) history	11 submissions · 11 cleared · 1984-1987