FDA 510(k) Premarket Notification

K833369 EARLY DETECTOR

CLEARED

Aug 2, 1984
310 days to decision

K833369 · Product code: **KHE** · Hematology
Source: https://www.510kdatabase.net/k833369/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Occult Blood (KHE)
Date received	Sep 27, 1983
Decision date	Aug 2, 1984
Days to decision	310 days
Third-party review	No

APPLICANT

Company	**Warner-Lambert Co.**
Location	Mchenry, IL, US
510(k) history	50 submissions · 50 cleared · 1979-2003