FDA 510(k) Premarket Notification

K831813 CO-OXIMETER CONTROL

CLEARED

Jul 28, 1983
52 days to decision

K831813 · Product code: **KHG** · Hematology
Source: https://www.510kdatabase.net/k831813/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Whole Blood Hemoglobin Determination (KHG)
Date received	Jun 6, 1983
Decision date	Jul 28, 1983
Days to decision	52 days
Third-party review	No

APPLICANT

Company	**United Diagnostics, Inc.**
Location	Mchenry, IL, US
510(k) history	12 submissions · 12 cleared · 1979-1989